THE HIGH COST OF PRESCRIPTION DRUGS

HEARING

BEFORE THE

SELECT COMMITTEE ON AGING
HOUSE OF REPRESENTATIVES

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THE HIGH COST OF PRESCRIPTION DRUGS

FRIDAY, MAY 18, 1990

U.S. HOUSE OF REPRESENTATIVES,
SELECT COMMITTEE ON AGING,
Washington, DC.

The committee met, pursuant to notice, at 10:32 a.m., at the Main Administration Building, Essex Community College, Baltimore, Maryland, Hon. Helen Delich Bentley (acting chairman of the committee) presiding.

Members present: Representative Bentley and Blaz.

OPENING STATEMENT OF CHAIRMAN HELEN DELICH BENTLEY

Mrs. BENTLEY. Good morning. I'd like to start out this hearing this morning, sponsored under the aegis of the Select Committee on Aging, by thanking my very good friend and favorite Brigadier General, Ben Blaz, who's a Congressman from Guam, for joining us here today. This is the second time that Ben has come to Essex Community College for us and we do appreciate his taking the time to do it. I also want to take a brief minute to thank our panels of distinguished witnesses for taking their time out of their busy schedules to tackle this issue, which is a very complicated and a very emotional one, as all of our witnesses certainly know. This is an issue that has interested me for some time based on the experience I've witnessed at home from the rising costs of what my husband is paying for prescription drugs as well as the comments of a number of my friends and constituents who have been complaining about what appear to be escalating costs.

One other note, given the numbers of people in the audience, there will undoubtedly be some questions for the witnesses and we're going to ask all of you to write down your questions on cards so that we can then present them. It will speed up our process a great deal. Please put your name at the top of the card so that we will have it for the record which will be part, as I said earlier, of the official record of the House Select Committee on Aging.

I want to start today by reading a few lines from a document that probably has a very familiar ring to you and you're going to be surprised when I tell you where it's from and how old it is.

The drug market is in reality a captive market. More often than is the regular rule, the individuals who need these drugs do not order them themselves. They are ordered by the family physician. They cannot substitute any other product. The drug prescribed is the one and only one that can serve their need. It isn't like transportation, for example. If we cannot afford an automobile, we can utilize the service of a bus and our health is not in any way harmed and if we do not have enough money to buy a television set, well, we get along without one. When our health is

involved, however, we must depend upon the products of medical research and products which it produces to assure the maximum degree of treatment for the illness.

That statement was made back in December of 1959 by Senator Smathers from Florida during the first comprehensive hearing that was held to examine drug prices. Senator Smathers was no enemy of the brand name industry but he was, just as I am today, very concerned about the high prices that seniors were paying and he was determined to explore all appropriate avenues in terms of isolating the problem.

Many of the arguments and counterarguments that were heard back then are still being heard today, although with new technologies as well as new legislative initiatives. For example, back then we had no Medicaid nor Medicare programs—the dynamics have changed somewhat in the market. However, rest assured that many of the fundamental questions raised in the hearings held between 1959 to 1962 remain as do the potential solutions. Let's hope that 30 years from now, we will have more answers than questions. With that in mind, we'll turn it over to our witnesses unless Ben, you have an opening statement that you'd like to make.

STATEMENT OF REPRESENTATIVE BEN BLAZ

Mr. BLAZ. I just want to commend you, Helen, for holding this hearing. The reason I'm here is because when Helen Bentley goes after something, she always gets what she's after and I'd like to be associated with it because she's a winner. But I really think the reason she invited me is because I'm fast approaching that point in my life where I will also be going after prescription drugs and she wants to help me.

I just need to add that ironically, this is a month that's designated at least in my district, the entire month, as the "Month for the Elderly."

In my community, to give you an idea of the distinction between communities in the country, we do everything we can to make sure that in the autumn of their lives they have absolutely so little to worry about. I realize my community is very small but it really stuns me when I go to various districts in the mainland United States and find out the disparity between the way that our elderly in my community are treated.

For instance, it's very extraordinary in our community to have a home because a home is with a small letter "H." It's a real home, is where we keep our elderly. We don't have these homes as you have here in the States. We don't have cards that we send on certain birthdays. We don't have to do that because everybody comes to the family home.

So, I participate in this hearing to make sure that I can contribute to the understanding that how dreadful it is as our hair grays, those of us who have some, as I turn gray and gold, they get grayer and golder because we worry about what's going to happen next and what a terrible thing when it should be like that.

So, Helen and I sit in the Select Committee on Aging and believe me, in these days when we're talking about weapon systems and everything, the other day on Alzheimer's and related diseases, I made the point. I didn't think I'd ever say it but as a retired military guy and I want to mention, by the way, this is particularly a

thrill for me to be here because this is where Jimmy Deveroux served for so long. I knew Jimmy Deveroux but in any case, it makes you wonder if we could just get the left wing of a B2 and concentrate it on the things that we're talking about or maybe the right wing because I gave the left wing yesterday to the Human Rights Caucus.

In any case, I'm pleased to be here and I want to congratulate you, my friend, for your tenacity and for your vigorous pursuit of what we're trying to do here. Pleased to be here, Helen.

Mrs. BENTLEY. Thank you. Ben, like General Deveroux, was one of our very special Marine Corps heroes.

Our first panel this morning consists of a constituent, Mrs. Media McLaughlin of Dundalk; Lynda Nersesian of the Pharmaceutical Manufacturers Association, Dave Miller who's the executive director of the Maryland Pharmacists Association; and from the University of Maryland, Dr. Francis Palumbo who's the associate director for the Center for Drugs and Public Policy.

We're going to start off with Mrs. McLaughlin. I want to thank you, Mrs. McLaughlin, very much for joining us here today and we'd like to hear your story.

Mrs. MCLAUGHLIN. Thank you.

STATEMENT OF MEDIA McLAUGHLIN, DUNDALK, MARYLAND

Mrs. MCLAUGHLIN. Thank you. Good morning, Madam Chairwoman, Congressman Blaz. My name is Media McLaughlin and I live in Dundalk, Maryland. I'm very pleased to be here today before the Select Committee on Aging to tell my story.

I have a muscle disease called myasthenia gravis. Basically, the drug Mestinon is used to treat this disease. This drug is only manufactured by one company in the world, Roche Laboratories. At one time, the Myasthenia Gravis Foundation had drug banks where we could purchase this drug a little above wholesale.

Last fall, without warning, Roche Laboratories notified all participating drug banks that they would no longer furnish medication at discount prices. We were dealing with Washington Hospital Center, Washington, DC.

At present, I am taking 18 to 20 Mestinon tablets per day. I buy 1,000 at a time, which is roughly a 50-day supply. In April, 1989, I was paying $61.40 for 1,000. Between April and August, the drug banks were closed. In August, the Foundation found a new supplier, R.X. America in Salt Lake City, Utah and the price went to $174 for 1,000. Now the price is $200 for 1,000.

I might add that I take four other prescription medications daily. One of these is a nongeneric drug called Imodium. The price is $62.16 per 100. I take from two to four tablets per day. We do have insurance which is $75 deductible, 80 percent for nongeneric and 100 percent for generic. My husband will be retiring soon and we lose all of our insurance. There is no way we will be able to pay these prices.

I usually file major medical claims semi-annually and it takes 6 to 8 weeks to be reimbursed by the company. Ninety percent of the time they make mistakes and I have to resubmit. In fact, I just got 1988 straightened out in February of 1990.

I would like to know why the drug companies cannot furnish these medications cheaper or come up with generics and I would also like to know why the insurance companies cannot pay 100 percent of the costs in cases where a generic is not available.

Thank you, Madam Chairwoman and Congressman Blaz, for having me here today.

Mrs. BENTLEY. Thank you, Mrs. McLaughlin, and we'll come back to you in a few moments with some questions.

Dr. Palumbo?

STATEMENT OF FRANCIS B. PALUMBO, Ph.D., ESQ., ASSOCIATE DIRECTOR, UNIVERSITY OF MARYLAND, CENTER ON DRUGS AND PUBLIC POLICY, BALTIMORE, MARYLAND

Dr. PALUMBO. Madame Chairwoman, Congressman Blaz, thank you for allowing us the opportunity to be here today to discuss the issue of the prices of pharmaceutical products with you.

The proportion of the population comprising the elderly is expected to continue to increase. In addition, the elderly account for a disproportionately large percentage of personal health care expenditures. While they accounted for only 11 percent of the population in 1980, they accounted for 29 percent of health care expenditures. While Medicare pays for approximately half of the elderly's personal health care expenditures, over 25 percent is paid out of pocket, the rest being funded from private insurance sources. These out-of-pocket expenditures are increasing at an increasing rate. It is estimated that for 1990, the elderly would spend almost 19 percent of their income on personal health.

At the present time, with very few exceptions such as immunosuppressives or injections administered in a physician's office, Medicare only pays for drugs received while in the hospital. A few so-called Medigap policies may cover outpatient drugs, but this is certainly not the rule. In 1986, for example, the elderly spent $9 billion, that's right, billion—on prescription drugs. Of this, $7.3 billion, or 81 percent, was paid for out of pocket. In addition, in structuring the Medicare Catastrophic Coverage Act of 1988, Congress estimated that one of every six elderly patients would spend over $600 per year on prescription drugs in 1991.

The elderly are generally a sicker population who suffer from multiple chronic illness. This necessitates the long-term use of chronic medications for such conditions as hypertension, heart disease, diabetes and arthritis. New medications for these conditions are continually reaching the market but the high price may become an impediment to the elderly's access to care.

Not only is prescription drug coverage for the elderly almost nonexistent but the cost of drugs at the manufacturer's level continues to out-pace the general rate of inflation. In 1989, for example, the inflation rate was 4.6 percent. Prescription drug prices from manufacturers, however, increased by 9.7 percent during that same period. Given that many elderly are either on fixed incomes or pension plans which may provide a small cost-of-living increase, the purchase of prescription drugs is an increasingly serious economic problem.

There is little argument that prescription drugs are one of, if not the most, cost effective forms of therapy. They tend to be taken for granted because they are safe and effective and have been around for decades. In addition, they do not afford the consumer immediate gratification as would a meal or a new coat. They are however, along with public health measures, largely responsible for the increased life expectancy of our population. Consider the consequences of untreated infection, hypertension or heart disease, for example. Not only would patients suffer but the mortality rate from selected illnesses would be extremely high without prescription drugs.

There are many questions concerning the reasons for the high cost of a commodity that may be necessary for life or to prevent pain and suffering. The answer involves a complex set of issues and is much more complicated than charges that the major drug companies are attempting to reap excessive profits.

Gross profit as a percentage of sales for the research-intensive pharmaceutical companies is approximately 25 percent before taxes. This compares with an average of about 8 percent among other corporations in the nondurable manufacturing sector. It is very important to note, however, that the profit motive serves as the impetus for the discovery of many drugs in use today. Without this profit motive, many drugs might never have been discovered. The pharmaceutical industry spends about 16 percent of its total revenue on research and development compared with average research and development expenditure of about 3 percent among the Nation's other manufacturing industries.

The U.S. pharmaceutical industry is a for-profit, competitive industry. Although it receives a few tax concessions on such things as orphan drugs, it funds most of the research and development on drugs in this country. The cost to bring a new drug from its initial inception to the market is virtually astronomical. This cost is estimated to be approximately $125 million. Our regulatory system is complex and costly. A great deal of research must be conducted to assure both the safety and effectiveness of marketed drugs. The Food and Drug Administration is charged with assuring the safety and effectiveness of drugs entering the U.S. marketplace and it requires much of a company before approving marketing.

The industry has been criticized for its methods of and expenditures on promotion. Naturally, this expense is built into the price which a company charges for its products. The industry argues that this is necessary to survive in a competitive environment and that it is the most efficient way of adequately informing physicians in a timely manner of the benefits of a particular therapy.

The U.S. patent system contributes to the high price of sole source prescription drugs. These, unlike generic drugs, are available from only one source—the innovator company—until the patent expires. During this period of patent protection, there is no head-to-head direct price competition for that particular product. On the other hand, there is competition in the marketplace since there are likely to be related, although not identical products, which a prescriber might choose in many instances. Thus the patent system does not really allow a company to charge unlimited amounts of money for its patent-protected products.

When the patent expires on a brand name drug, it becomes available from a number of manufacturers as a so-called generic drug. This is defined as a drug that is chemically identical to the innovator, brand-name drug. In 1987, generic drugs accounted for approximately $5 billion or 20 percent of the U.S. prescription drug market. The typical generic drug is often priced at 30 to 40 percent below that of its counterpart, brand-name drug. The generic drug industry is a price-sensitive industry made up of many small firms and research-intensive firms who sell generics. It does not routinely engage in a substantial amount of research to discover new drugs. Its research is generally confined to assuring that its product is equivalent to the brand name product within the limits allowed by Federal regulations. Ironically, increases in research and increased competition may force the price of new breakthrough drugs even higher by decreasing the time an innovator company has a patent monopoly. Since a competitor may market an even better drug at any time, companies often believe that they must make their profits when they can.

Public confidence in generic drugs was recently shaken by the problems which surfaced at the Food and Drug Administration involving the dishonesty of some FDA staffers and individuals from generic manufacturing companies. A generic manufacturer must, however, comply with all Federal regulations in order to market its drug. It must, for example, adhere to good manufacturing practices as defined in the regulations.

Research-intensive pharmaceutical manufacturers often engage in what is known as multi-tier pricing. They offer substantial discounts to Federal Government agencies such as the Department of Defense and the Department of Veterans Affairs as well as to non-profit hospitals and to health maintenance organizations. The companies can afford to do this since these entities combined account for only about 14 percent of their total sales. Wholesalers and community pharmacies make up the rest. The community pharmacy, where most elderly receive their medications, is unable to take advantage of these discounts, so cannot pass them along to its patients in the form of lower prescription prices.

What has been done recently to deal with the problem of the high drug prices incurred by elderly patients? Congress passed the Medicare Catastrophic Coverage Act of 1988 to afford the elderly some relief from prescription drug costs of a truly catastrophic nature. The deductibles are structured so that only 16.8 percent of the elderly could take advantage of the out-patient prescription drug program in any given year. Yet, for these people, it could have made the difference between solvency and poverty.

The act also provided increased hospitalization benefits. Congress repealed the Act, however, due to pressure from the elderly over financing their own benefit. In addition, the true nature of this act was inadequately communicated to the elderly so that there was a great deal of confusion over the benefits they would receive. They in turn exerted a great deal of pressure on the Congress who elected not to alter the act but to repeal it. Thus, the elderly are now left with no protection against catastrophic prescription drug costs.

Senator David Pryor from Arkansas has proposed legislation to help reduce drug costs to State Medicaid programs for welfare re-

cipients, both young and old. He has proposed the formation of a National Pharmacy and Therapeutics Committee and the formation of State Medicaid buying groups. As a result of his efforts, at least one pharmaceutical company has offered a proposal to reduce its prices to State Medicaid programs in exchange for coverage of all of its products by those programs.

While Senator Pryor's proposed legislation does seek to reduce drug prices, it does not address the problem of the non-Medicaid elderly who must continue to pay for their drugs out of pocket. In fact, one might pose the scenario that if companies lower their prices to Medicaid agencies, they may decide to raise their prices in the private sector to compensate. After all, one must consider the fact that the pharmaceutical companies cannot offer the same preferential price to all customers that they offer to less than 15 percent of their total accounts. Thus, the elderly who pay for their own prescriptions could be at an even worse disadvantage.

The problem of high prescription drug cost to the elderly will surely continue until the Congress takes action designed to assist all of the elderly, not merely those who already receive benefits under State Medicaid programs. Congress should review carefully the events surrounding the enactment and repeal of the Medicare Catastrophic Coverage Act of 1988 and then take appropriate positive action.

I sincerely appreciate the opportunity to be here today to talk with you. Thank you.

Mrs. BENTLEY. Thank you, Dr. Palumbo, for a very important statement covering the treatment of the elderly as you see them through the hospital.

Mr. Miller?

STATEMENT OF DAVID G. MILLER, P.D., EXECUTIVE DIRECTOR, MARYLAND PHARMACISTS ASSOCIATION, BALTIMORE, MARYLAND

Mr. MILLER. Good morning, Congresswoman Bentley, Congressman Blaz. On behalf of the officers, trustees and members of the Maryland Pharmacists Association, I'd like to take this opportunity to thank you for inviting us to be with you this morning.

As Congresswoman Bentley mentioned, I am the executive director of the Maryland Pharmacists Association. Our organization represents more than 1,200 pharmacists in all areas of pharmacy practice in our State, the independent retail pharmacy on the corner most of us are familiar with, the larger chain operations such as Peoples, Giant, Drug Fair, Rite Aid, as well as pharmacists who are in practice in the hospitals, in long-term care settings, education, industry and many other areas.

I also am a pharmacist educated at the University of Maryland School of Pharmacy. I am licensed to practice and I do some relief work for Lykos Pharmacy in Timonium, Maryland.

This morning I would like to take the opportunity to focus my remarks on two areas of prescription drug pricing that the pharmacist deals with. The first is how we as pharmacists calculate the prices that are charged to the patient and the second is those areas that pharmacists believe that we can have a positive impact on the

undeniable escalation in drug prices that we as professionals and consumers have witnessed over the past several years.

In any given prescription, there are essentially two components that make up the price that a patient pays. These are the actual cost of the drug product from the manufacturer, the wholesaler, as well as a service component or dispensing fee as we call it in the profession. The prescription dispensing fee is an amount that is added to the cost of the prescription drug product from the pharmacy. That includes such hard or fixed costs as the price of the vial or bottle that the tablets or capsules go into. It also includes the bag that the prescription is dispensed in and the instruction and warning labels that are placed on the vial that tells the patient how the medication should be correctly taken.

The dispensing fee also includes variable costs such as an allocation for the salaries of the pharmacist who fills the prescription, the technicians or support personnel in the pharmacy department, those who assist in the processing of the prescription, the lights, the water, the electricity, telephone and the required State and Federal license and also a component for a profit on each prescription.

Also, too are included in those costs the miraculous technology that we in pharmacy have experienced through the introduction of computers in all aspects of our practices. Those computers allow us to instantaneously access your prescription drug history records, your allergy and sensitivity information, information pertaining to your third party or insurance programs and it enables us also to cross-check for drug-drug interactions which can be potentially life-threatening.

The way pharmacists calculate the variable costs of our dispensing fees is that we estimate what the total cost for all of those individual items will be in any given year. Then we also project by approximately how many new and refill prescriptions we will fill in our pharmacy during that year. By dividing our costs by the total number of prescriptions, we have an average dispensing fee. What a pharmacist does then essentially is spreads the costs of his activities in filling prescriptions in a pharmacy across his entire patient population.

One of the most common questions that many pharmacy patients have is why does the prescription cost so much in one pharmacy as compared to another pharmacy? Shouldn't the exact same prescription that I have filled at one store cost the same as in another store? The answer of course is that there are no two pharmacies who are exactly alike. One pharmacy, which may provide delivery services, special patient counseling, late-night hours, emergency dispensing and has a sophisticated computer system for your use, will have a higher variable cost, a higher dispensing fee, for its prescriptions.

Compare that to another pharmacy which provides nc services except for filling the prescription and handing you the bag. That pharmacy will have a lower variable cost and therefore a lower overall dispensing fee. As the old adage goes, in pharmacy, you do get what you pay for. Some patients are satisfied with no service whatsoever and are willing to accept discounted pharmacy programs while other pharmacists and other patients, especially in the

elderly population, may value and require paying a little more for those pharmacies that do provide that extra service.

That essentially is how the pharmacist determines his portion of a prescription drug price. The greatest component of the prescription drug cost though is not the dispensing fee. In fact, in any given prescription, the average dispensing fee represents only $3 to $4 total of the total price. That, in fact, as Senator Pryor has shown in several of his Congressional hearings, has remained constant over the past 5 to 6 years. The biggest cost then remains in a prescription is the price of the drug itself.

Now as a pharmacist, we have two avenues by which we may obtain our prescription drugs. One is through a local wholesaler who specializes in stocking and warehousing drugs. The other is to purchase the drug directly from the pharmaceutical manufacturer. Unfortunately, more and more manufacturers are abolishing their direct purchase programs because of the cost of distributing and maintaining accounts for some 50,000-odd pharmacies nationwide.

In either situation, the cost of the drug is set, not by the pharmacist, but by either the wholesaler or the manufacturer. Pharmacists too have been shocked by the continual and relentless price increases in the cost of prescription drugs. You see, we too must also pay more for the same drug each time a drug price is increased by the manufacturer or a wholesaler.

In preparing for this morning's presentation, one of our members provided me with old copies of the Red Book and I've brought them with me this morning. The Red Book is essentially pharmacy's Sears Catalog. It lists all of the prescription drugs and nonprescription drugs that are available to a pharmacist and it also lists what a pharmacy would expect to pay if they ordered that prescription drug from either a wholesaler or a manufacturer.

Now, at random this morning in preparing for the testimony, I selected three commonly dispensed brand name drugs and what I wanted to look at was how the prices had increased over the past several years. In 1982, a pharmacist could obtain a bottle of 100 tablets of Inderal, 40 milligrams, which is used to treat hypertension, for $10.31. In 1986, the same bottle costs $20.85, a doubling of the price in 4 years. The May 15th, 1990 wholesale price reported by First Databank—this is the price current for this week—is $36.85.

In 1982, a pharmacist could purchase 100 valium 5-milligram tablets for $13.99. In 1986, the price was $26.81. In 1990, this week's price is $44.28. Another common drug is lanoxin, .025 milligrams. It's used to treat congestive heart failure, a very common drug for the elderly. In 1982, 1,000 tablets, which is the most commonly purchased size by a pharmacy, was $12.76. The same bottle cost the pharmacist $39.60 4 years later. Today, if I were to order a bottle of 1,000 lanoxin tablets, I would expect to pay $65.32.

That's an increase from approximately $13 less than 8 years ago to almost $66 this year. Except for changes in package design and in the case of inderal and valium, changes in the tablet design—not the component but the way the tablet looks—these are the same drugs by the same manufacturer in the same bottle size as they were 8 years ago.

Pharmacy is perhaps the only health care profession in which an actual product is provided directly to a patient along with a service. As such, we are especially sensitive to the impact that price changes have on our patients. Imagine how we feel when we have to explain to an elderly patient who is on a fixed income that the prescription he or she filled last month has gone up in price once again. In that patient's eyes, we, the pharmacists, are responsible for his or her higher out-of-pocket expenses, not the manufacturer, who has raised their prices to us.

Pharmacists have identified two areas that have directly resulted in higher prescription costs. These are discriminatory pricing policies by manufacturers and the increasing number of third party prescription benefit plans. Let me touch briefly on the discriminatory pricing policies. This is one area in which we have been actively seeking a solution as a profession. Some manufacturers indulge in marketing practices whereby they sell the same drug products that the pharmacy in the retail setting pays at ridiculously discounted prices to other classes of trade. Dr. Palumbo alluded to this in the special prices that are given to nonprofit hospitals, the Department of Defense. A drug company with a new antidepressant may wish to sell that product to a hospital at a price far below the cost of the drug to a retail pharmacy in an attempt to train physicians to write for that drug product. Although a hospital benefits from these low prices, the patient ultimately pays for that benefit when the prescription is filled in the community pharmacy at the higher cost.

Although this is currently legal, the practice is questionable. Maryland Pharmacy has been instrumental in passing a resolution in the Maryland legislature to send a clear, strong message to you, our Federal representatives, that such discriminatory pricing is inappropriate and must be investigated.

The second area that has directly resulted in higher prescription costs to patients is third party prescription insurance. Not too long ago, patients paid for their prescriptions with cash. Now it is not unusual for a pharmacy to have more than 40 to 50 percent of its prescription business paid by third party insurance companies. Now, how does an insurance company impact on the price of a prescription? Because the insurance company sets the dispensing fee that can be less than the average dispensing fee that the pharmacist has calculated for his business, he has to make up the difference in order to be able to pay his bills and stay in business by increasing the dispensing fee he charges to the cash-paying customers. It's what we call a cost-shifting.

In addition, most third parties have extensive rules and regulations about what size quantity is allowed, the number of refills, mandatory generic substitution and much more. Pharmacists must be current in all these rules or else he or she is not reimbursed for the prescription. That too is a loss that has to be made up by collecting higher cash prices from his patients. As an example, in April 19 of 1990, the Maryland Pharmacists Association published a directory of third party prescription plans and their rules. Less than 1 month later, there have already been more than 26 changes to this directory. Despite advances in technology that allows eligibility checking and copayment and deductible calculations through

electronic means, most pharmacies still are unable to keep up with the many restrictions and changes in programs. The magical prescription card that some patients use to have their prescriptions filled for only a $2 copayment, is partly responsible for the increased prices that the other patients pay for in cash.

There are many reasons for the increased costs of the drugs that will be addressed by other members of these panels. We in pharmacy, however, ask that you recognize that our control over prescription drug pricing is limited. As professionals, we resent being placed in the position of having to continually explain to our patients why prices continue to escalate and we ask that you work with pharmacy to help resolve this problem.

I thank you for the opportunity to be here.

Mrs. BENTLEY. Thank you, Mr. Miller, for that excellent statement.

General Blaz and I will now ask some questions of the panel and then we will have these panelists stay with us so at the end we can ask questions that may come from the audience.

Mrs. McLaughlin, you've described your medical claims reimbursement process as extremely slow. Is this because of the complexity of the forms, disagreements over coverage, or simply slowness of the company and do you have any suggestions on how this can be speeded up?

Mrs. MCLAUGHLIN. I would say it's slowness of the company and disagreement over the forms. The form is not complicated. It's just that when they start dividing the generic and nongeneric. In one form, they pay 100 percent. The other, they pay 80 percent. That's when things started getting messed up because apparently, they have people working for them, that don't know the correct level. Or perhaps they don't have a book they can use and they wind up paying the 80 percent across the board. Then you go back to try and clarify, and they say, well for that you've got to see somebody else. It's an out-of-town company. They do not have a 1-800 number and by the time you find out the name of a person, that person is no longer working in that office.

Mrs. BENTLEY. You're not confused when you start to fill out your form? I mean, you're very clear on your 80 percent and 100 percent?

Mrs. MCLAUGHLIN. Right.

Mrs. BENTLEY. It's just when you get it back that you find problems have been created?

Mrs. MCLAUGHLIN. Right.

Mrs. BENTLEY. Doing a few quick calculations, it appears you are taking about $2,000 worth of Mestinon and Imodium per year along with additional costs for the other drugs and other medical expenses. Would this be about right?

Mrs. MCLAUGHLIN. That's about right. Out of pocket right now, we are paying roughly $900 a year.

Mrs. BENTLEY. Out of pocket.

Mrs. MCLAUGHLIN. That is correct.

Mrs. BENTLEY. For you?

Mrs. MCLAUGHLIN. Right. Just for me.

Mrs. BENTLEY. Do you have any idea what might be the experiences among your friends and relatives?

Mrs. MCLAUGHLIN. Many of the people that I know have the $1 or $2 cards and they could care less. They're not looking down the road like I am. I'm looking to the time when we don't have the insurance and we've got to figure out a way to pay for these drugs.

Mrs. BENTLEY. When you don't qualify for insurance?

Mrs. MCLAUGHLIN. Right.

Mr. BLAZ. What would you do then, if you get to that point?

Mrs. MCLAUGHLIN. I don't know. I see no way that my husband can retire.

Mr. BLAZ. He's going to have to retire.

Mrs. BENTLEY. What age is your husband now?

Mrs. MCLAUGHLIN. He's 59.

Mrs. BENTLEY. Is he in good health?

Mrs. MCLAUGHLIN. He's got a 40 percent back disability.

Mrs. BENTLEY. Does he have to take prescription drugs to relieve the pain?

Mrs. MCLAUGHLIN. No.

Mrs. BENTLEY. So you are concerned about what's going to happen in 3 to 5 years, or 3 to 6 years?

Mrs. MCLAUGHLIN. Exactly. The only way he can retire is if I die and I'm not planning on dying.

Mr. BLAZ. You'd be back in 3 days probably anyway, wouldn't you?

Mrs. MCLAUGHLIN. Sir?

Mr. BLAZ. I was planning on getting back in 3 days myself.

Let me just ask you a number of questions that would weigh heavily, I imagine. I wouldn't be able to feel comfortable about my 1,000 drugs that I take to make me well if I had that in the back of my mind.

Is this a common dilemma for people in your group?

Mrs. MCLAUGHLIN. I was caught at a time when the disease and the medication were more or less in an experimental stage. I first was put on something like three pills a day and I spent a year crawling and I went from that up to 20, back to 18. I've been fine for, I would say, 15 years, but now my neurologist says there is no way he would put anybody on that number—high dosage that I am on because they've learned more about it now but there's no way that I can come back down.

Mr. BLAZ. Because your system has gotten used to—

Mrs. MCLAUGHLIN. No, it is not an addicting drug but I refuse to live as a vegetable and without the medication, I cannot function.

Mrs. BENTLEY. So you need that level?

Mrs. MCLAUGHLIN. Yes.

Mrs. BENTLEY. Okay, thank you. We'll certainly keep you very much in mind as we proceed on this and I know there are probably many, many Mrs. McLaughlin's out there.

Mrs. MCLAUGHLIN. I'm sure there are.

Mrs. BENTLEY. People who are facing the same problems.

Dr. Palumbo, in talking about the rising costs and the problems, I just want to make a general comment about some of the pharmaceutical profit figures that I've seen thrown around—that range from 300 percent to 550 percent. I want to focus on the example of a fictitious person who owns a candy factory and is making two candy bars. That person spends money on overhead, on personnel,

on sugar, and all of that has been kept at a Somewhat reasonable cost because of sugar controls and then the baking ovens and slicing machines, et cetera.

Let's say the price of one candy bar was 20 cents but over the last several years, it jumped from 20 to 40 cents which is a 100 percent markup. Well, obviously after all the bills have been paid, the 100 percent price increase is not much of a profit.

Now, if you broke that "reasonably priced" 20 cent candy bar down, it probably would only cost about 4 cents, maybe even 3 cents, to make, but no one would ever think about saying a 400 percent markup is ridiculous. A company that registers a 10 percent profit per year at the end of the year isn't doing that bad.

In the case of prescription drugs, if you're Merck and you say that you raised prices 5 percent for 1989, you're in hot water. Are prescription drug prices rising too fast in your view?

Dr. PALUMBO. In my view, they are. They have consistently outstripped the rate of inflation. I just mentioned some figures from last year but the fact of the matter is, if you look at this over time, the price of medical care in general and prescription drugs which are part of medical care has consistently exceeded the general inflation rate. General inflation rate would tend to include increased prices of supplies and chemicals and equipment and so forth, as the candy store example that you used. There are other factors that come into play, some of them being the decreased patent life on a pharmaceutical, some of them being an effort to regain some of the losses that a company might have taken on products that didn't pan out.

Nevertheless, the price—

Mrs. BENTLEY. In other words, the cost of research and development. Perhaps a lot of money went into research on a product that didn't pan out.

Dr. PALUMBO. Yes, which is often the case in the pharmaceutical industry. There are many products that look promising in the beginning and never make it to the market stage because they're not as effective as once thought or the side effects are unacceptable, so they abandon them.

I think the problem comes in here though with the products that Mr. Miller has mentioned which have been on the market for years and those products continue to rise at an increasing rate. I don't think we argue too much about the price of a new product that immediately hits the market to treat an illness except, I must say there was one exception and that was AZT—the pricing of AZT when it first came onto the market—and there were a number of hearings at the State level with regard to the pricing of AZT.

The next year, the company dropped it 25 percent. I think this was an example of the company feeling that someone else would be coming out with an alternative, equally acceptable treatment for AIDS in a very short period of time and they would essentially lose most of their market share.

So, it's not an easy question. There are many factors, but to get back to your initial question, the price of pharmaceuticals was more than double the general inflation rate last year.

Mrs. BENTLEY. I get a lot of mail from my constituents who just can't keep up with these rising drug prices, which is of course one

of the reasons I wanted to have a hearing today, let's find out more about them. You have stated that just solving the Medicaid problem isn't enough. Could you elaborate a bit more extensively on this, keeping the State of Maryland in mind?

Dr. PALUMBO. Certainly. Maryland has some elderly people in its Medicaid program as do other States. The State pays for the drugs for these people. The current legislative proposal that is out there, Senator Pryor's proposal, is an initiative to reduce prescription drug prices to the States for Medicaid patients. It does not address, however, Mrs. McLaughlin, for example, and that is my major concern with the present legislative initiative.

Mrs. BENTLEY. The people who are just not covered?

Dr. PALUMBO. That's correct.

Mrs. BENTLEY. Ben?

Mr. BLAZ. Dr. Palumbo, when health is wanting, individuals are willing to pay anything. I've heard people say, "I'd give anything just to feel better tomorrow" and they can do that for a while. Then they get to the end of the line. In your experience, is there any evidence or any indication that because of this sentiment that the people who know this and make the medicine and manufacture the medicine take advantage of this situation?

After listening to your testimony, there's so many factors and so many variables that go into the equation that I won't make any general saying because I didn't realize, and your testimony was excellent. I'm assuming from this that you're an attorney as well so I take your word as an officer of the court or I believe you.

Dr. PALUMBO. Well, I got one vote.

Mr. BLAZ. So, could you help me with that?

Dr. PALUMBO. I have never seen any direct evidence to the effect that the pharmaceutical companies are trying to capitalize on the pain and misery of suffering people. I certainly know that when a company is developing a drug, it looks at the potential market for that drug. The company looks to see how many people are afflicted, for example, with myasthenia gravis, with tuberculosis or hypertension and then makes a business decision as to whether it should enter into the market with its product.

So from that perspective, it is looking at the numbers with regard to pain and suffering, disease, and so forth in the United States and making business judgments based on that.

I would not go so far as to say though, however, that the company is going to say, "well, let's see what we can get out of these people." I think there are too many competing factors that prohibit a company from absolutely doing that. It may happen in some isolated cases certainly but there are usually alternate therapies available. If we take hypertension, there are many, many types of drugs that a physician can use to treat hypertension within the same drug class.

One of the high-cost drug items today to the public and private sectors are the H-2 antagonists which are used to treat ulcers. There are at least three products on the market within this drug class, not chemically identical, but close enough where one might be used in place of the other. That keeps a lid on the price unless of course, all the companies got together and decided to raise the

price. I certainly don't have any evidence of that. Again, it's a marketing issue.

Mrs. BENTLEY. That would also be an anti-trust issue, I would think if they did that.

Dr. PALUMBO. Absolutely.

Mr. BLAZ. Can I ask one more question?

Mrs. BENTLEY. Certainly.

Mr. BLAZ. Are you sure?

Mrs. BENTLEY. Absolutely.

Mr. BLAZ. She's a very tough leader, I tell you.

No one has testified or no one has mentioned anything about the impact of foreign pharmaceuticals. Do you have any comment on that? We have problems, as you know that, large firms.

Dr. PALUMBO. Yes.

Mr. BLAZ. But given your background, I imagine you probably have read or dealt with it directly? What gems of wisdom might you offer?

Dr. PALUMBO. If your question is related to the quality of foreign pharmaceuticals, I don't think there is really any evidence of a widespread problem in the United States today. A foreign pharmaceutical manufacturer must meet all U.S. Food and Drug Administration regulations as well as comply with the Food, Drug and Cosmetic Act. They must go through our FDA in order to market their drug in this country.

The regulations, the Food and Drug Regulations, do allow for foreign clinical studies to be used as part of the documentation for getting a drug on the market in this country but they have to be closely monitored and well-documented in order for that to occur and the Food and Drug Administration rarely will let a drug onto the market solely on the basis of foreign clinical studies.

So I really don't think there is a problem with that from a quality standpoint. I think the problem would be in competition, of course, from a price perspective.

Mr. BLAZ. Thank you, Dr. Palumbo.

Mrs. BENTLEY. Piggybacking on that question of the General's, are there any indications that you know of and I'm going to ask the Pharmaceutical Manufacturers Association this one when they come up, are there any indications that the FDA moves the foreign applications any faster than those of the domestic American manufacturer's?

Dr. PALUMBO. I don't know if you can use FDA and "fast" in the same sentence. But I certainly have not seen any evidence to that effect.

Mr. BLAZ. What we're really after is, has anyone invented a Ponce de Leon water that can stop the aging process so that we can stay in the Congress for a long, long time?

Dr. PALUMBO. No.

Mr. BLAZ. Okay, thank you.

Mrs. BENTLEY. Mr. Miller, you were talking about your dispensing fee earlier and you indicated that a dispensing fee might be $3 to $4 per prescription—I think this is the figure you used. Is there any formula in the Baltimore area where all of those in Baltimore are charged the same, or the fees go up at the same time or anything like that?

Mr. MILLER. No, Mrs. Bentley, absolutely not, because pharmacies are in the same situation as the manufacturers are. We are not allowed to set prices. That is anti-trust.

Mrs. BENTLEY. So if each one on their own—

Mr. MILLER. Each pharmacy on his own sets his own prices.

Mrs. BENTLEY. Each chain would do their own?

Mr. MILLER. Right.

Mrs. BENTLEY. The independent pharmacist would set their own and they would raise them according to their own overhead costs?

Mr. MILLER. Exactly. There are also variations within an individual chain. It would not be uncommon for a pharmacy that is on Kent Island and its main headquarters where the majority of its stores are here in downtown—the Kent Island store may have either a higher or actually a lower dispensing fee because their overhead may be lower due to costs.

So, you can't even say it's different between one independent and one chain. It's even different within the same chain.

Mrs. BENTLEY. Okay. You had also referred to the massive amount of paperwork that sometimes is required—the claims processing, reports to State agencies, patient profiles, et cetera, and you're doing a lot of this now by this modern technique, computers, that Ben and I have still got to learn all about.

In this way, one of the systems that's called for the computer network is called a PCS, a prescription card system. Another has the acronym of PAID. I would appreciate it if you could briefly tell me how each of these works.

Mr. MILLER. Certainly. PCA is Pharmaceutical Card Services. They're based in Scottsdale, Arizona. PAID Prescription Plan is, I believe, based in New Jersey. Both of these are a type of prescription drug insurance program. Let's say for example that you work for a large corporation "A" and one of their benefits is to provide you with insurance coverage.

What they would do as a corporate benefit to you is they would go to either PAID or PCS as a prescription insurance administrator. PCS would then, for example—say we have a selection of 200 different types of plans from which you can choose and let's say Plan No. 103 covers vitamins, doesn't cover birth control pills, covers injectables, does not cover Rogane, the new drug for hair treatment, but, PCS Plan No. 233 will cover the vitamins and the birth control pills but will not cover the injectables and will not cover Rogane.

So there's a wide variety of plans that a company can select from.

Mrs. BENTLEY. The company is the one who usually selects the plan, not the individuals?

Mr. MILLER. That's correct. The company selects the plan from PCS or PAID that best meets their needs in providing the benefits to their individual employees.

Now, that's very easy for the company. On the other hand, the pharmacist has to keep track of all 250-odd PCS plans and their different rules because if he does not comply correctly—if he fills a prescription that is not covered, he will not be paid for that. Same situation with PAID pharmaceuticals. If you don't comply with the

rules of their, I believe, 25-odd plans, you will not be reimbursed properly or your reimbursement will be cut down.

That essentially is how a third party system works for the pharmacist. Each company has different rules, different regulations, different standards by which they expect you to practice. Each copay may be different depending on what the company decides they wish to set for their employees' share of their prescription benefit and also the processing is much different and that again is one of the areas that directly result in higher cost eventually to the cash-paying customers.

A PCS program has recently introduced what we call a recap box and a recap box allows instantaneous electronic transmission of pharmaceutical data directly to their headquarters in Scottsdale, Arizona. The information is typed into the computer. It is sent out to PCS. They say yes, this prescription is covered for this patient and this is what you should charge them for their copay or deductible. That comes back through the telephone wire to the pharmacist while the patient is in the store, usually within 35 to 40 seconds and that information is taken care of. PCS is the only major pharmaceutical third party insurer or administrator who is currently doing that.

The majority of claims are either transmitted directly to the administrator on magnetic tape, if you are computerized, on handbills, what we call universal claim forms, claim forms similar to the claim forms you're required to fill in for your insurance for your major medical. We send those in and then we can wait anywhere from 7 days for payment in the case of Blue Cross Blue Shield of Maryland who is very timely in their payment. It's usually about 14 days for Maryland Medicaid, also very timely in their payment but for other companies like PAID, it is not unusual for a pharmacist not to be reimbursed from anywhere between 45 days, 60 days.

We do have a local company here in Baltimore who provides third party insurance benefits for some of the carpenters unions and the glaziers. They currently are now at 6 months behind schedule in paying for their prescription drug benefits.

Meanwhile, the patient's already received and taken their medicine, and the pharmacist is still waiting for his money.

Mrs. BENTLEY. That's a cost item.

Mr. MILLER. That is a cost item.

Mrs. BENTLEY. Okay.

Ben?

Mr. BLAZ. You know, Helen, I remember the day when I'd rather be sick than go to pharmacies because of the way the pharmacist looks at me. Now, we have Mr. Miller here, I'll tell you, Mr. Miller. Your testimony this morning is really enlightening to me. Very well presented, well educated, well reasoned, and I'm really impressed because obviously we have a new generation of pharmacists. I'll tell you, they used to have Benjamin Franklin glasses peering behind you like that and scaring the hell out of you. And now you come along, and you're a sight for sore eyes, I'll tell you.

Let me ask you a question on mail order types. We've got to bear in mind that the mission of this whole operation is for the poor folks back home, you know, because they don't always have the

time to learn all this other stuff. They'll go to any extent just to get it cheaper.

How do you feel about mail order pharmaceuticals?

Mr. MILLER. Politely?

Mr. BLAZ. Politely, yes.

Mr. MILLER. Politely. First off, thank you for the compliment, Congressman.

Mrs. BENTLEY. He's now taken off his glasses.

Mr. BLAZ. He's taken off his Benjamin Franklin glasses.

Mr. MILLER. The education of pharmacists has changed within the past 10 years and I have people like Dr. Palumbo who is one of my professors, to thank for that. The emphasis now is not on the drug product so much as it is on the patient and I think that you will see the new generation of pharmacists over the next 20 years will not look down at you and will actually talk to you.

In regards to your questions on mail order, mail order is a very large thorn in the side of pharmacy and I say that because it goes completely in the face of what pharmacy is about. Pharmacy and the education that is being instilled in the pharmacists that are graduating in the next 2 weeks from the University of Maryland and all over the country is that the patient is your No. 1 concern.

You have to be there for that patient. You have to look at their prescription. You have to assess whether the prescription is appropriate for the patient, something that is relatively recent. In the past, nobody questioned the physician and nowadays that's not uncommon for the pharmacy to make that intervention.

It is real difficult to take care of a patient over a telephone. It's extremely difficult to take care of a patient when the pharmacy is in Arkansas and you're a patient in Pennsylvania. There are some questions that the Pharmacy Association here in Maryland and in every other State as well as on a national level have raised about mail order prescription services and that is that in the State of Maryland, we have a very thick green book that are the pharmacy laws and regulations and how a prescription and a pharmacy is dispensed and regulated in our State.

Our Board of Pharmacy has those regulations to protect the public health of the citizens of Maryland. If as a citizen you send your prescription to New Jersey to a mail order firm to be filled, our State Board of Pharmacy has absolutely no control over that pharmacy whatsoever. There is nothing that—

Mrs. BENTLEY. Who does? Who does?

Mr. MILLER. Theoretically, it's the New Jersey Board of Pharmacy but bear in mind, the New Jersey regulations may be entirely different than Maryland. Yes, most of them are the same but there are some significant differences. I give you as an example the State of New York. In New York, you are required to complete a triplicate prescription form for any narcotic prescription dispensed. In Florida, you don't have a triplicate prescription form and if a patient mails a prescription from New York to Florida to a mail order house to be filled, they have essentially circumvented the law that New York State has put in place to protect its citizens in New York. That is one concern.

The area of service is another concern. If you, Mrs. Bentley, need a prescription filled this weekend, you know how to get hold of

your pharmacist. What happens to the patient who mails the prescription and waits 3 days, waits 5 days, waits a week and it still has not been delivered? If you as a patient were to come to a pharmacy and say, I mailed my prescription in and I have not received it and I need to start on it right away, what am I supposed to do?

The pharmacist has no idea what you mailed off. They can contact your physician, yes, but in that case, you're relying on the community pharmacy to bail you out of a situation which essentially is an economic disadvantage to him.

One of the not-uncommon trends we are seeing in pharmacy now with third parties is that they are proceeding from strictly local pharmacy prescription benefits to encouraging their subscribers and their beneficiaries to use a mail order option and what they do is they will say, your prescription benefits cover a week to 2 weeks worth of medication that you can have filled at your local pharmacy and anything greater than 2 weeks worth has to be sent to a mail order firm.

Now, if that becomes an increasing trend and if more patients send their prescriptions through the mail to a warehouse operation somewhere, 200, 300 miles away, the local pharmacy will not be there when you need to get those medications for acute care, when you need assistance from a pharmacist because they won't be able to stay in business.

So if the American public is satisfied with no service and no contact with pharmacists, then mail orders should be their option and I don't think that is where most people want to see their prescriptions handled.

Mr. BLAZ. Well, doctor, lawyer, professor, senor Palumbo, what do you think about that?

Dr. PALUMBO. I find it hard to disagree with what Mr. Miller has said. I think one of the major problems with mail order firms is their ability to comply with conflicting State laws and I think this is a major impediment to the safe use of prescription drugs through the mail.

In addition to triplicate prescription forms—some States have laws or regulations on patient counseling. Some States have laws or regulations on the proportion of pharmacy technicians per pharmacist in a particular facility. Some do not. Others have regulations on the handling of controlled dangerous substances that might differ from State to State and still be in compliance with Federal law.

Mail order firms basically have to be able to comply with the laws of the States into which they mail prescriptions in order to, I think, operate safely and I don't see evidence at the moment that they are interested in doing this based on the testimony of their own lobbyists at the State and Federal levels.

Mr. BLAZ. Thank you.

Mrs. BENTLEY. Thank you.

I do have a couple more questions but I'd rather ask them of the two of you when we have the other panelists at the end. So, at this point, we will break and have our next panel come up which is Miss Lynda Nersesian from the Pharmaceutical Manufacturers Association and Dave Banta from Blue Cross Blue Shield, the Director of Pharmacy Relations.

Let's start with Miss Nersesian.

STATEMENT OF LYNDA L. NERSESIAN, DEPUTY VICE PRESIDENT, GOVERNMENT RELATIONS, PHARMACEUTICAL MANUFACTURERS ASSOCIATION

Ms. NERSESIAN. Madam Chairman and Representative Blaz, I would like to summarize my statement if that's all right and ask that the full text be included in the record.

I am Linda Nersesian, deputy vice president of government relations for the Pharmaceutical Manufacturers Association. PMA represents more than 100 research-based pharmaceutical companies that develop, discover and produce most of the prescription medicines used in the United States.

I appreciate this opportunity to appear before the select committee during this hearing. I hope that this committee will keep in mind three key factors concerning the pharmaceutical industry as this hearing proceeds and the first is that it is a comparatively small industry. If you were to congregate all of my companies into one company, we would still be only No. 7 of all the Fortune 500 companies.

No company commands more than 8 percent of the market. Even our largest competitor does not command 8 percent of the market and one would have to congregate all of the sales of our largest 22 companies in order to reach 75 percent of that market. What I'm trying to tell you is that we are a fairly small industry.

Secondly, PMA companies devote a far higher percentage of their sales to research and development than any other high-technology industry. I think that you heard Dr. Palumbo mention that in fact this is a very, very large percentage of our sales. Chairman Waxman's House Subcommittee on Health and the Environment estimated that from 1982 to 1986, 34 percent of our profits were devoted to R&D and I would suggest that no other industry can match that record.

Mrs. BENTLEY. That was 34 percent?

Ms. NERSESIAN. Yes, ma'am. That's what their study indicated.

Thirdly, the industry's share of the U.S. health care dollar has decreased sharply from 12.4 percent in 1965 to 6.8 percent in 1987 and to my knowledge, no one seriously questions the fact that this small share of the health care expenditure pays for the most cost-effective form of therapy. For example, in its first 10 years, the anti-ulcer drug Tagamet saved $4 billion in the U.S. alone.

Although the cost of prescription drugs represents a declining portion of this Nation's health care expenditures, the Prescription Drug Price Index has increased more in the past few years than the overall Consumer Price Index. I should point out, however, that the Prescription Drug Price Index is still below the CPI established in 1967. In other words, in the 1960s and 1970s, we were below the CPI. It's only recently, in the last decade, that we have begun to exceed the Consumer Price Index.

As an association of competitors, PMA does not and of course, according to the anti-trust laws, we cannot get involved in the individual pricing decisions of our members but I can note that the

period of time during which our companies can recover their enormous investment has shrunk due to several factors.

Foremost is the unprecedented surge in competition from generic products as soon as the patent expires on the pioneer drug. So in other words, normally you think of a patent as being 17 years. In the case of the pharmaceutical industry, that patent is usually averaging about 7 years. In 1984, Congress enacted the Price Competition Act and as a result of that Act, the generic comes on the market right away. The day the patent on the pioneer drug expires, that generic drug is right on the market and we estimate that the first year alone, we lose 35 percent of the market. By the second year, we've lost 50 percent of the market, just to give you an idea as to what the time period is in order for us to recoup our investment.

Other major factors which shorten the time during which the companies can recover their sizable expenses include the intense competition both within the industry and outside of the industry, long delays in FDA's approval of new drugs and increasing foreign competition from both developed countries that have targeted this industry and newly-industrialized countries that blatantly condone patent piracy.

As noted in the May 13th, 1989 article in The Economist, "During the past decade, the profitable life-time of drugs has declined while the costs of testing and marketing, which now must be worldwide in order to recoup big investments, have escalated." The Center for the Study of Drug Development at Boston's Tufts University estimates that the average cost to bring a new medicine from discovery to the pharmacy exceeds $230 million.

Now, I heard Dr. Palumbo quote $125 million and that was a sizable investment, but the newest figures are 230. They exceed that.

Now, I want to discuss—Mr. Miller who you heard from before who I would suggest seems like a very good pharmacist, someone whom I would rely on, but I do want to suggest that he made an allegation about discriminatory pricing and Chairman of the Judiciary Committee on the House side, Chairman Jack Brooks, had sent to the FTC a letter asking whether in fact the allegations that we price basically illegally is true and I must say that the FTC gave a resounding answer back in about a 7-page discussion. They did a complete review of the allegations and stated that this is absolutely not the case and I will supply you with that letter. I don't have it with me but I think that you will be convinced that in fact, this is not the case.

I'd like to discuss—while I can't get into individual drugs—I know that back in March I was listening to a morning TV show and of course my ears perked up when I heard they were doing a study of some of the pharmacies in the Los Angeles area. They were looking at five pharmacies and seeing what the different pricing was in each pharmacy and Mr. Miller did cite Inderal and they happened to do a study of Inderal in those five pharmacies. Now, this particular drug had the least amount of convolution per pharmacy but nonetheless at one pharmacy, it was $42.30; at another pharmacy, it was $30.90; and by mail order, it was $23.95.

Mrs. BENTLEY. The two pharmacies were in the same area and the mail order?

Ms. NERSESIAN. That's right. I just want to read one quote to you: "We priced five drugs at five typical pharmacies in the suburbs of Los Angeles and here's what we found" and I can provide you with the transcript. It's interesting.

Mrs. BENTLEY. Okay. We'd like to have that.

Ms. NERSESIAN. It is interesting. I'd also note for you that this happened with another drug that they surveyed. I won't mention the drug unless you'd like me to but they found that 100 pills were $144.05 at one pharmacy; they were $200 at another; and by mail order, $139.65. So, I realize that this is not an answer to Mrs. McLaughlin but one has to be a consumer where drugs are concerned as well. You do have to shop around and that concludes my statement.

[The prepared statement of Ms. Nersesian follows:]

Statement

Pharmaceutical Manufacturers Association

LYNDA L. NERSESIAN

DEPUTY VICE PRESIDENT, GOVERNMENT RELATIONS

PHARMACEUTICAL MANUFACTURERS ASSOCIATION

BEFORE THE

SELECT COMMITTEE ON AGING

UNITED STATES HOUSE OF REPRESENTATIVES

MAY 18, 1990

Madam Chairman and Members of the Committee:

I am Lynda L. Nersesian, Deputy Vice President of Government Relations for the Pharmaceutical Manufacturers Association. PMA represents more than 100 research-based pharmaceutical companies that discover, develop and produce most of the prescription medicines used in the United States. I appreciate this opportunity to appear before the Select Committee during this hearing. I hope my comments will be helpful to the Committee.

Madam Chairman, as this Committee keenly appreciates, the miracle medicines invented, developed and produced by America's research-based pharmaceutical industry have been enormously successful in lengthening lives and in improving the quality of life of older Americans and of people of all ages around the world.

The death rates from many diseases have declined impressively in recent years. In the cardiovascular area -- the diseases that are the leading killers of older Americans -- the death rate has dropped 42% in the last 20 years. Medicines have played an important role in that progress, starting with the thiazide diuretics of the 1960s through the beta blockers of the 1970s to today's calcium channel blockers, ACE inhibitors and cholesterol-lowering and anti-clotting drugs.

While progress against hypertension, stroke and other cardiovascular diseases has been impressive, that group of illnesses still afflict millions of people in the prime of their seniority. And the aging of America has created new and even more demanding challenges for our whole system of health care, including the pharmaceutical industry. Major diseases that are among the most chronic and intractable in our society now primarily afflict older Americans. These include lung and colon cancers; Alzheimer's Disease; osteoarthritis, and osteoporosis, to name just a few. Recent surveys by PMA determined that companies have 221 medicines in human tests or awaiting approval by the Food and Drug Administration to treat 23 diseases that primarily strike the elderly, as summarized in Table 1.

New Medicines for Older Americans Survey

Companies	77
Medicines	221

Cardiovascular Disease		Cancer		Other	
Hypertension	38	Colon	20	Depression	16
Congestive Heart Failure	28	Breast	16	Alzheimer's Disease	15
Coronary Artery Disease/ Angina	17	Lung	14	Rheumatoid Arthritis	15
Atherosclerosis	9	Skin	11	Osteoarthritis	10
Arrhythmia	8	Prostate	10	Osteoporosis	10
Peripheral Vascular Disease	6	Mouth (Oral Cavity)	1	Parkinson's Disease	6
Heart Attack (Coronary Thrombosis; Myocardial Infarction)	7	Other	25	Adult Onset Diabetes	4
Stroke (Cerebral Thrombosis)	6			Glaucoma	3
Other	2			Gout	2

Table 1

Older Americans need these new medicines now in development. And they need even more the advanced therapies now in the very early stages of research. As you recently pointed out, Madam Chairman, we spend over $167 billion a year to treat medical conditions of the elderly, and we must "learn how to better treat and prevent the diseases that too often accompany old age." History confirms that the vast majority of new medicines needed by the elderly will come from the research-based pharmaceutical industry.

Fully half of the $7.3 billion of private funds being invested by PMA companies this year in research and development is devoted to medicines for diseases that primarily afflict older Americans. Figure 1 shows the total research and development expenditures of PMA companies since 1977, and compares those expenditures -- which have doubled every five years since 1970 -- with the total research and development spending of the National Institutes of Health for all biomedical research.

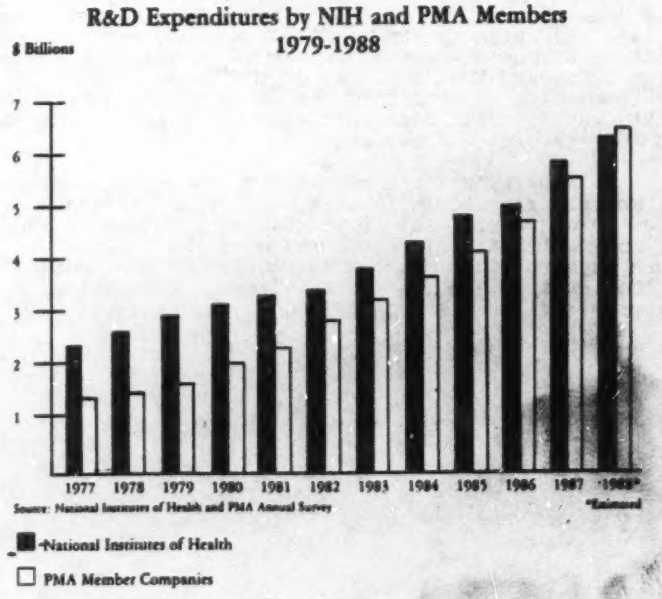

Figure 1

In human terms, the new medicines that will result from our industry's R&D will have a profound effect on how long Americans will live and on their quality of life in their later years. But these new medicines will also have an enormous economic impact. Alzheimer's Disease, virtually unrecognized a generation ago, has been estimated to cost our nation more than $50 billion a year -- about twice the entire annual U.S. sales of PMA members. Former Secretary of Health, Education and Welfare Joseph A. Califano, Jr. recently estimates that "each one-month reduction of dependency for our citizens over 65 means a $4 billion savings in annual health care and custodial costs alone."

We hope that this Committee will keep in mind three key characteristics of the research-based pharmaceutical industry as this hearing proceeds:

(1) It is a comparatively small and highly competitive industry. If the worldwide sales of PMA members were to be combined in one company, that company would rank no higher than seventh among the Fortune 500 companies. No company commands more than 8% of the U.S. market, and the sales of 22 companies must be combined to reach 75% of that market.

(2) PMA companies devote a far higher percentage of their sales to R&D than any other high-technology industry. Last year, the industry invested 16.3% of its sales in R&D, an increase from 10.2% in 1965, as shown in Figure 2. In a staff report issued in 1987, Chairman Waxman's House Subcommittee on Health and the Environment estimated that over 34% of the sales revenues resulting from price increases of prescription drugs from 1982 through 1986 was invested back into R&D. No other U.S. industry can match that record.

(3) The industry's share of the U.S. health-care dollar has decreased sharply from 12.4% in 1965 to 6.8% in 1987, as illustrated in Figure 3. And to my knowledge no one seriously questions the fact that this small share of the health-care expenditure pays for the most cost-effective form of medical therapy. For example, in its first 10 years, the anti-ulcer drug Tagamet saved $4 billion in the United States alone.

R&D Expenditures as a Percentage of U.S. Pharmaceutical Sales

(Includes U.S. sales plus exports)

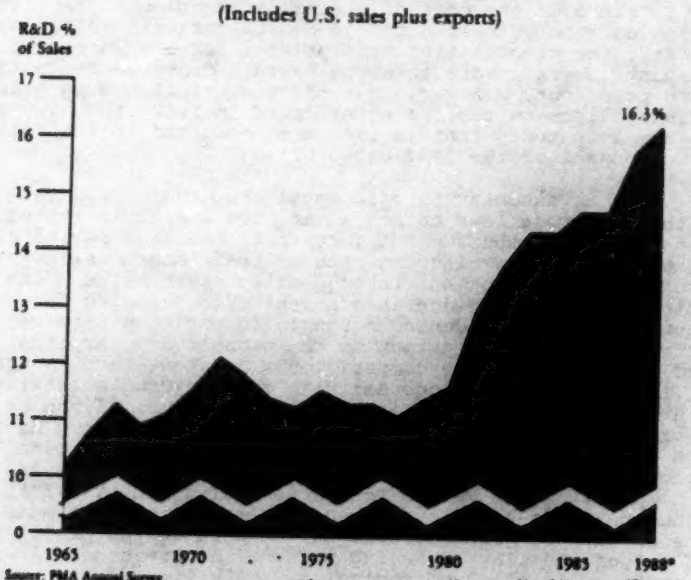

Figure 2

Drugs (and Other Nondurable Medical Products) as a Percentage of National Health Care Expenditures

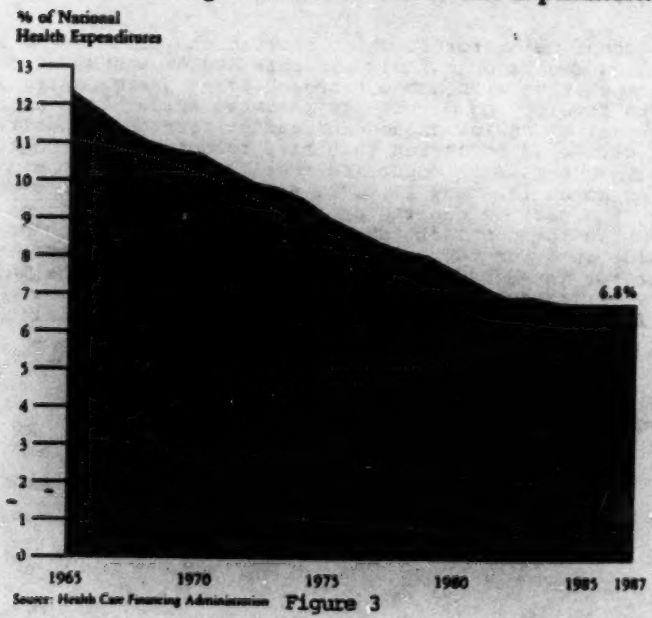

Figure 3

Prices of Prescription Drugs

Although the cost of prescription drugs represents a declining portion of this nation's health-care expenditures, as I have noted, the prescription drug price index has increased more in the past several years than the overall Consumer Price Index. I should point out, however, that the prescription drug price index is still below the CPI established in 1967; that is, drug prices are less today than in 1967 when compared to the "all-items" component of the 1967-based CPI.

As an association of competitors, PMA does not -- and under the antitrust laws cannot -- involve itself in the pricing decisions of our members. But I can note that the period of time during which our companies can recover their enormous investment in research and development through sales revenues is being dramatically compressed due to a number of converging forces. Foremost is the unprecedented surge in competition from generic products as soon as the patent on the pioneer drug expires, spurred by the Drug Price Competition and Patent Term Restoration Act of 1984. That Act, together with generic drug substitution laws in the states, results in a virtual collapse of the market for a brand-name drug soon after the patent on the drug expires. Because generics can be made so cheaply, this has drastically shortened the product life cycle of brand-named drugs. The Drug Price Competition and Patent Term Restoration Act itself is analogous to a two-act play. We have already seen the economic effects of the pro-generic substitution part of the play. The second act of the play -- having to do with patent term restoration -- is only now beginning. Only five of the 61 pharmaceutical patents whose terms have been extended would have expired by now had extensions not been granted. And no patent has been extended more than two years because of the way the law was written.

Other major forces which shorten the time during which the companies can recover their sizeable R&D expenses include the intense competition within the research-based pharmaceutical industry to develop and market new patented drugs, long delays in FDA's approval of new drugs and increasing foreign competition from both developed countries that have targeted this industry and newly industrialized countries that blatantly condone patent piracy. As noted in a May 13, 1989 article in The Economist, " . . . during the past decade the profitable lifetime of drugs has declined while the costs of testing and marketing, which now must be worldwide in order to recoup big investments, have escalated." The Center for the Study of Drug Development at Boston's Tufts University estimates that the average cost to bring a new medicine from discovery to the pharmacy exceeds $230 million.

Increases in R&D vs.
Increases in Drug Prices

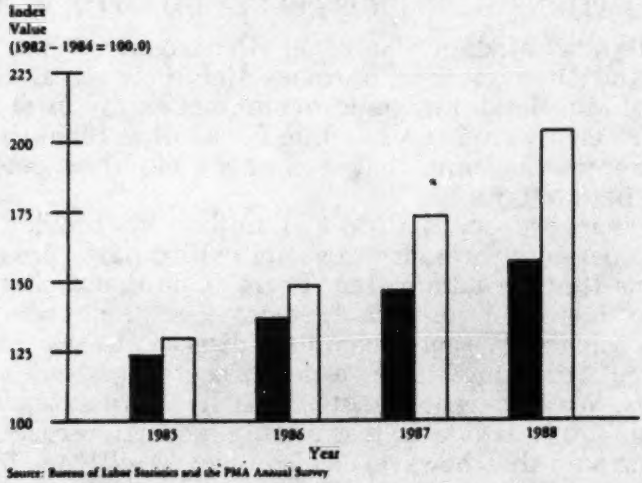

Figure 4

With respect to price increases of prescription drugs in recent years, the largest single factor in manufacturers' costs, but not the sole factor, has been the sharp increase in investments in R&D. Figure 4 compares the prescription drug price index, established at the 1982-84 base, to an "R&D index" based on that same starting period. R&D spending in our industry far outstrips the price index. Costs of labor, materials and promotion have also increased.

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Madam Chairman, that concludes my prepared statement. I would be pleased to respond to any questions you may have.

Mrs. BENTLEY. Thank you.
Mr. Banta?

STATEMENT OF DAVE BANTA, DIRECTOR OF PHARMACY RELATIONS, BLUE CROSS BLUE SHIELD OF MARYLAND

Mr. BANTA. Madam Chairman, Congressman Blaz, I am Dave Banta, the Director for Pharmacy Relations for Blue Cross Blue Shield of Maryland. I'm going to summarize my brief remarks also and start off by saying that Blue Cross Blue Shield finds itself in the same predicament that a number of other people have expressed here today.

Last year, we spent over $66 million to provide prescription drugs to patients through the various third party prescription drug programs that we administer. There is no doubt that prescription drugs as has been testified to today, are the modern miracle of medical science. We have complete disease classes that only a few years ago would have been a death sentence. Now, we are rid of smallpox. We can treat diabetes. Our lives are extended. The quality of our life is extended. It is a truly modern miracle.

Having said that however, I also have to tell you that the cost of prescription drugs is the fastest growing portion of our current budget. We for many years—

Mrs. BENTLEY. Excuse me. Is that faster than hospital costs?

Mr. BANTA. Faster than hospital costs, right.

We for many years took prescription drugs for granted. They were there, as Dr. Palumbo has indicated. They were available. They were relatively inexpensive. They are, in our opinion, the most cost-effective portion of the health care delivery system when you consider the cost of the illnesses avoided and the cost of other modalities of treatment.

So we're wrestling with something that we've taken for granted but now because of the sharp and recent escalation in cost, comes under increasing focus. We are very concerned with that as well since we are the third party payer. I think in your opening remarks, you made mention of this and we have observed this as well. Prescription drugs are unlike any other consumer commodity you can name in that the patient or the recipient of the product is not the originator of the demand for the product. We're out here as a payer for the product and this results in some unusual relationships that you don't usually find and avoids marketplace pressures that might hold down some costs.

So this is an irony that it is so valuable to us but seems to be somewhat out of control. It's a pass through for us. We operate a traditional prescription drug card program. As Mr. Miller alluded to, there are several other competitors, PCS, PAID and so forth.

We happen to be the largest third party prescription drug program in the State of Maryland. We operate in the State of Maryland. We believe we have a good relationship with the pharmacy provider community. As Mr. Miller indicated, our processing time is considered good and I would say that we probably have a 95 percent participation rate among pharmacies in the State.

We have done some things internally to look at rising costs. We don't control the costs either. The costs are set by the manufactur-

er. When a patient goes into a pharmacy with a prescription drug card from Blue Cross Blue Shield, that prescription is filled. The patient usually pays a copay—the most common is $5—and leaves the pharmacy with that medicine. The pharmacist submits either on a universal claim form which you've already heard about or a magnetic tape—they're becoming increasingly computerized—to Blue Cross Blue Shield. We reimburse the pharmacist the cost plus a dispensing fee, less the patient's participation on the form of the copay.

One of the things that we have in place to begin to address these things is the phasing in of a drug utilization review program. Now, what we do with this is we attempt to identify patients at high risk for adverse drug reactions such as overutilization, underutilization, drug interactions. This is done by taking a historic pharmacy claims paid data, putting it through a computer which analyzes the data to identify these patients that are at some risk. Individual patient profiles are produced. These are then reviewed by a committee of pharmacists and physicians to determine if they are in fact a medically important problem.

If they are, if it's determined that they are, then intervention letters or informational letters are sent out to the physicians and the pharmacists involved so we can correct the problem.

Now, DUR, as it's known, is primarily a quality of care program but we have found that there are cost savings to Blue Cross Blue Shield and its client companies because we avoid hospitalizations, we avoid doctor's visits, if we can take away the drug interactions and if patients become more compliant with their prescribed therapy. That's the idea behind DUR.

In addition, we do operate a generic drug program. We have a list of maintenance drugs for which we allow larger quantities to be dispensed. All of these things are in the nature of benefit design so that we can try to tailor our program to make the best use of the prescription drugs and prescribing behavior, but, again, we don't control the costs. All we can do is manage what flows through our system and that's what we're attempting to do.

We are modifying some of our policies to look at high-tech drugs such as the parenteral and the chemotherapy medicines that are delivered at home now. We want to start covering those. We want to offer a benefit to our clients to cover that because that can be one of the catastrophic drug costs that we see some of our subscribers getting into.

We're also looking at changing some medical policies covering what's called off-label use of drugs, that is, new uses for old drugs, drugs that have received FDA approval for one set of circumstances and then through practice, physicians discover that it's useful in another condition, begin writing for that. We want to begin examining that to see if we want to cover those as well.

At any rate, I have provided my written testimony. We are delighted to be here to participate in this. We share the concerns of others who have testified here today about the rising costs of prescription drugs. We don't believe that there are any real easy solutions to this. I think Congress looked at this issue with the Medicare Catastrophic legislation. I think that's where the real crunch is at this point. As long as the PMA companies are going to be

paying for tomorrow's drug discoveries out of today's profits, we have to ask ourselves how far do we want to cut into that? Where do we control that?

If they're looking for the cure for cancer or Alzheimer's or AIDS or whatever, you know, that's part of what comes out of these price increases. What I think we need to do though is examine how we can help our seniors and we'd be glad to participate or provide any perspective that we can from our part of it.

[The prepared statement of Mr. Banta follows:]

STATEMENT OF DAVE BANTA BEFORE THE
HOUSE SELECT COMMITTEE ON AGING
ON FRIDAY, MAY 18, 1990

Last year Blue Cross and Blue Shield of Maryland spent over $66 million to provide prescription drugs to patients through its various prescription drug programs. There can be no doubt that these prescription drugs represent a modern medical miracle in the treatment of disease and the improvement in the quality and length of our lives. When compared to the cost of other modalities of treatment and the cost of the illnesses prevented, prescription drugs are the most cost-effective part of our health care delivery system. Conditions, such as diabetes, that only a few years ago would have been a death sentence, are now treatable. Whole diseases, such as small pox, have been eliminated because of the miracle of prescription drugs.

Having said this, let me also add that the cost of prescription drugs is the fastest growing portion of our budget at Blue Cross and Blue Shield. According to the Bureau of Labor Statistics Producer Price Index, prescription drugs rose 9.7% in 1989 as compared to an increase in the consumer price index of 4.8%. At Blue Cross and Blue Shield, we anticipate an increase of 18 to 20 percent in our prescription drug budget based on patterns of increased utilization and a shifting of prescriber preference to newer, more expensive prescription drugs. It was recently announced by industry experts that it costs prescription drug manufacturers about $200 million on average to bring a prescription drug from its initial discovery through the testing, development and approval process to market. This extraordinary expense is reflected in the cost of the end product. We are now seeing new product launches from drug manufacturers appearing on the market priced at over $1.00 per tablet. Some of these represent significant therapeutic breakthroughs and some do not.

And so, we are faced with the great irony of prescription drugs. They are our greatest weapon against illness and disease, but the costs associated with them are rising at an alarming rate. For many years, the cost of modern medicines was taken for granted. In fact, at one point in the mid seventies, the overall cost of prescription drugs actually declined in comparison with the consumer price index. Prescription drugs were widely available and comparatively inexpensive. This contrasts sharply with the recent dramatic rise in prescription drug costs today. This contrast has forced those of us who pay for prescription drugs on behalf of our patients to closely examine the dynamics of the prescription drug business. Prescription drugs are unlike any other consumer commodity that you can name. The recipient of this consumer product is the patient. However, the physician, not the patient, is the originator of the demand for the product. In many cases this transaction is often paid for by a third party such as Blue Cross and Blue Shield. Because of these unusual relationships, normal competitive marketplace forces do not operate well in this environment. As long as manufacturers must pay for the research and development for future drug discoveries from today's patent protected drug products, these price escalations are probably inevitable. Still, we must take steps to attempt to contain rising prescription drug costs while striving to maintain a high level of quality of care. We welcome the interest of Congress in these issues. There are no simple solutions to these complex problems.

What cost containment strategies has Blue Cross and Blue Shield of Maryland itself considered to address these circumstances? We are phasing in a drug utilization review program for most of our lines of business which will identify patients at high risk for adverse drug reactions - such as over-utilization, under-utilization, and drug interactions. While primarily driven by quality of care considerations, it is understood that appropriate drug use results in cost-avoidance through decreased hospital admissions and physician visits. Prescription drug claims data are analyzed by computer to identify patients at risk and a profile of that patient's drug history is generated. These profiles are reviewed by committees of physicians and pharmacists to determine if they represent a medical problem. If they do, information letters are generated to the prescribers and pharmacists involved with patient care.

We either have in place or are considering a number of other prescription drug program benefit design changes which will augment our managed care approach to combat rising costs. Patient cost sharing through various deductibles and co-payments is an existing cost containment strategy. These can be flat dollar amounts, dual brand/generic copayments, straight deductibles, percent coinsurance or maximum benefit amounts. In addition, we are utilizing generic drug formularies, maintenance drug lists for larger quantities and eliminating coverage for certain less than effective drugs or drugs without therapeutic benefit. We are considering consumer, pharmacy and physician education programming, therapeutic outcome studies and prior authorization programs. We are concerned about the problem we all face in ensuring appropriate patient compliance in prescription drug therapy. The inadvertent mis-use of prescription drugs is a documented nationwide problem. We are reviewing internal policies related to the coverage of drugs which are prescribed for uses other than those specified by the FDA. And we are currently developing policies and methodologies for the coverage of the new high-tech home health care deliveries system for products such as parenteral nutrition and chemotherapy. These measures taken together indicate the concern we have at Blue Cross and Blue Shield about the rising cost of prescription drug therapy. It is our goal to manage these rising costs without sacrificing quality of care.

I am here to share with you our perspective on this issue and also to learn from others. Perhaps if we pool our thoughts on this matter we will begin to gain some understanding of the underlying forces involved in the ironic miracle of prescription drugs. On behalf of Blue Cross and Blue Shield of Maryland, I am very pleased to have the opportunity to participate in today's hearing and I will attempt to answer any questions you may have.

Mrs. BENTLEY. Thank you very much, Mr. Banta.

You mention that you're working on a way of covering chemotherapy treatments at home?

Mr. BANTA. Correct.

Mrs. BENTLEY. I take it that right now the only coverage that Blue Cross offers for chemo treatments are in the hospital?

Mr. BANTA. We are actually covering it in the home but we're doing it through our major medical program, as I understand it, and what we want to do is begin to cover that as a separate benefit item rather than just kind of lump it all together.

Mrs. BENTLEY. I see, in a whole package. Will it be cheaper by doing it that way to the consumer?

Mr. BANTA. I believe compared to a hospitalization, any time that we can get the patient into a home care situation, my understanding is that there is usually demonstrable cost savings.

Mrs. BENTLEY. Mrs. McLaughlin mentioned in her testimony that her insurance coverage will expire when her husband retires. Does Blue Cross Blue Shield have continuing coverage plans available for people in similar positions?

Mr. BANTA. This is not my area of expertise. I don't believe that she is currently covered under a Blue Cross Blue Shield plan. As she talked, it didn't sound like it was one of ours.

Mrs. BENTLEY. She just shook her head. She's not.

Mr. BANTA. We have had in the past an Over 65 Premium Program. I'm not sure if that's still being marketed or not.

Mrs. BENTLEY. We can check on that and might get the answer on that?

Mr. BANTA. I can find that out.

Mrs. BENTLEY. Okay.

Has Blue Cross Blue Shield been shifting away from flat copays to percent coinsurance?

Mr. BANTA. We have not—only in one program, a very small program, the premium program—changed recently. All the rest of our business is the cost of the drug to the pharmacist plus a dispensing fee which is $3.30 for most of our lines of business, $3 for the State of Maryland employees and retirees, less the copay that the patient has paid. The vast majority of those copays are a flat dollar amount at $5.

Mrs. BENTLEY. I see. You said $3.30. Is that what you allow a drug store for dispensing?

Mr. BANTA. Correct.

Mrs. BENTLEY. That's your allowance for what they charge?

Mr. BANTA. That's our dispensing fee and that covers their light, heat, rent, salaries, as you heard Mr. Miller testify.

Mrs. BENTLEY. Do you have any questions?

Mr. BLAZ. Yes, I do. Thank you, Helen.

My question has to do with the PMA. The research that's involved in this thing here is very costly as you pointed out. If I recall correctly, it was 34 percent of—

Ms. NERSESIAN. It's about $8.4 billion.

Mr. BLAZ. Which is exceedingly high. During that period of time when you submit something to FDA, I imagine that you're quite worried about whether or not they're going to get around to approving it. What expenses are involved in trying to protect the

secret to keep someone else in the meantime from discovering it. Is that a very costly thing for the company?

Ms. NERSESIAN. To answer your question, right at the outset we would go ahead and get a patent in order to protect our trade secret and our investment and then from the initial patent, it takes about 12 years to actually get the drug into the pharmacy. In terms of patent piracy, for example, abroad, you know that once we publish, we're very, very vulnerable to patent piracy. So, for example, in 1986, I think that the U.S. Trade Representative estimated that we're losing about $2 billion overseas in 1986 alone and all of industry is losing about $26 billion.

We're spending over $8 billion a year on research and that exceeds the National Institutes of Health combined which spend about $7.2 billion. It's an expensive process and of course, in terms of a patent, that is the only protection that you have for your intellectual property, for your ideas, your innovation and it is something that we safeguard.

Mr. BLAZ. If the process could be speeded up, I imagine you'd be in favor of that?

Ms. NERSESIAN. Right. It takes about 32 months from the time that a new drug application is filed at the Food and Drug Administration. It takes about 32 months for them to consider and approve the drug.

Mrs. BENTLEY. To consider and approve?

Ms. NERSESIAN. As far as the new drug application. As far as our clinicals and our preclinicals, that is also a review time but that is more in our court than in their court. The 32 months is in their court and abroad it's about 15.8 months. So there is a much faster procedure abroad than there is here.

Mr. BLAZ. What are your thoughts on generics?

Ms. NERSESIAN. I think that we have seen a flurry of activity in terms of investigating the generic drug industry but that no one has yet questioned whether in fact generics are up to standards. So in terms of the generic drug, there is a 20 percent equivalency rate. In other words, they are supposed to be as chemically equivalent to the name brand as possible.

In certain areas, I think that doctors are more likely to titrate, to get the patient established on a drug and that they don't often wish to vary that particular titration method but in other areas, it's, I think, fine to change from a generic to a name brand or a name brand to a generic.

I don't question that generics are not good drugs.

Mr. BLAZ. Thank you.

Mrs. BENTLEY. Let me ask you a question, Ms. Nersesian. You said the FDA approval process was about 32 months. Is there any kind of a deadline that the Federal Government or the Food and Drug Administration has set—a shorter period of time, for instance—that an application or a drug should be tested and should be out on the market?

Ms. NERSESIAN. Madam Chairman, it's actually statutorily set at 6 months. That is what it's statutorily set at. In fact, we think that it could be done a little bit quicker. I think that FDA is being scrutinized right now and that Congress in fact is trying to beef up the

FDA a little bit. They are trying to get them some help, give them some help in terms of their inspectors, et cetera.

Mrs. BENTLEY. We have some other questions but I think this applies to the whole panel and we'll ask Dr. Palumbo and Mr. Miller to come back up and join the two of you.

Mr. BLAZ. In the meantime, can I ask Mr. Banta a question here?

Mrs. BENTLEY. Sure.

Mr. BLAZ. Mr. Banta, you made a comment that there is no easy answer to the dilemma that we face and I was intrigued by that comment because the more I hear, the more I tend to agree that there are just too many parts of the equation, there are just too many. There's even a moral dilemma, a real serious dilemma of extending life to the point where you go from 50 years to 60 years and then to 70 years and now, we're going to extend it to 80 and it's going to get more and more complicated.

I'm just beginning to sense for the first time the dilemma say of people like yourself, now. In your own industry, you must be undergoing an enormous amount of turmoil trying to figure out how to continue to do this and be profitable because unless you are, you're just going to have to close shop.

Am I correct in assuming this is also causing you all some second, third and fourth thoughts about how to handle it?

Mr. BANTA. Very much so. While my area of expertise is in pharmacy and pharmacy relations, my understanding is that all of health care is looking at how do we manage and how do we, quite frankly, ration health care. There have been some books written about the high-ticket, high-technology forms of therapy that are available, who decides who will receive these, and from our perspective, who will pay for this? Those are very, very tough questions.

Mr. BLAZ. Thank you.

Mrs. BENTLEY. This is probably a question for Dr. Palumbo and Mr. Miller but any of you can respond to it after I bring it up.

One of my friends ran into a problem—and this again was one of the reasons that I got interested in this subject—where a doctor had far over-prescribed the amount of medication for a terminally-ill cancer patient. The person had from 7 to 10 days to live. The prescription that was written out and handed down was for 100 pills costing well over $100. When it was taken to the druggist, the druggist told his wife that this was ridiculous because he new the patients condition and had been aware of all the medication that the man had been receiving. The pharmacist said: "I'm just not going to give you that many because it's a waste of your money and if you need more, come back and we'll fill it then."

Is one of the problems associated with the high cost to the consumer for prescription drugs the fact that some of the prescribers, are not paying as close attention as they should be to the filling out the prescription?

Dr. PALUMBO. I think that's a major problem and I think that the problem is being addressed in large measure through the DUR or drug use review programs that Mr. Banta mentioned and in which Mr. Miller is participating through the Maryland Pharmacists Association.

For many years, at the University of Maryland, we have advocated the use of drug use review as a method to not only control the costs of prescription drugs but even more important to assure the appropriate prescribing of medications.

Mr. Miller can probably speak to the specific experiences of the DUR program at the Maryland Pharmacist Association but the literature is replete with examples of how inappropriate prescribing takes place at a fairly substantial level. I'm sure you recall the Inspector General's report about a year ago that spoke to this issue as well and well-documented the problems with inappropriate prescribing. The other part of the drug use review program is that not only do they identify instances of inappropriate prescribing or patterns of inappropriate prescribing but there are mechanisms to try and change behavior to bring it more into line.

Mrs. BENTLEY. Mr. Miller?

Mr. MILLER. Thank you, Mrs. Bentley. First off, I would like to make the observation that your friend's pharmacist did what a good pharmacist should do and that points out again the importance of service to individual patients in the community pharmacy.

I agree with Dr. Palumbo. There is a serious problem in the prescribing community and I believe it's not so much that the prescribers don't care, they really are not concerned at all with what their patients eventually have to pay for their prescription medications once they have them filled, but I think it's a question of education. Most prescribers really do not understand what the actual cost of a drug is and in fact, most are very surprised when their patients call back and say why did you give me a prescription for this mediation? It costs me $40.

There is an educational problem there and it is not uncommon for a pharmacist who knows a particular patient is in a restrictive financial situation to see if they can work out with the prescriber some form of alternative. Also bear in mind that prescribers are sensitive to the fact that some patients have third party prescription cards and almost every pharmacist can relate to you some instance of a physician prescribing a more expensive product so that they can try it out on a patient knowing full well that the patient is not ultimately the one that pays for the prescription medication.

So there's a little of both there and it's really an educational issue.

Mrs. BENTLEY. Mr. Banta, have you any experience in this area? Have any of your people complained about overprescribing?

Mr. BANTA. We are essentially the bill payers and we suspect that what Mr. Miller said is actually occurring. We don't have direct evidence of it but we do communicate with the pharmacy provider community and we have had some anecdotal information of this kind of behavior.

Mrs. BENTLEY. One of the members of our audience handles the health and welfare plan of a labor union, the IBEW. Prior to the beginning of todays hearing, when we were up here talking, he said that when they had issued the plastic card, or credit card as he called it for drug purchases, the price almost doubled in a couple of instances. So instead of continuing to use the plastic credit card, they went back to having the reimbursement directly to the patient.

Do you want to give the example and then we can discuss it and your name? [Directed to a gentleman in the audience.]

Mr. GUTHRIE. Thank you, Congresswoman Bentley. My name is Dion Guthrie. I'm the president and business manager of the IBEW for Local 1501. In that position, I'm also the plan administrator for our Local's health and welfare plan. Our particular—by the way, I've been in that position for over 21 years. The particular health and welfare plan that we have was put into effect in 1975. That particular plan is separate from our entire medical plan which is funded by the different employers. This particular health and welfare plan only takes care of eyeglass and prescription drugs. So we can isolate it pretty good in regards to our drug problem.

When we started in 1975, we started with a prepaid prescription drug plan. When you went to the drug store, you got your prescription filled out. You pay them right there. They fill out the card for you. You mail the card to Prepaid Drugs and you get reimbursed directly from our prepaid drug company in California who administers it for us. Normally, without problems, in 2 to 3 weeks, our members have our money back.

Mrs. BENTLEY. Let me ask you one question. Were your members able to go to any drug store that they wanted to?

Mr. GUTHRIE. Certainly. Our members travel all over the United States. So this really gives us a bird's eye view of the entire situation since they're going to drug stores all over the United States.

In 1985, our members pressured us about getting into a plastic card plan. That way we don't have to put the money up front. We can go right to the drug store, give them the card. We don't have to pay anything. In fact, as one of the gentleman mentioned here, the prescription drug plan in New Jersey, PAID prescriptions, was the very drug plan that we went to.

By the way, we have about 400 or 425 people that are in this particular health and welfare plan. In 1984, the total cost—and this is just the actual cost of the drugs, has nothing to do with overhead or administration or secretary fees or anything else—it's strictly the cost of the drugs—the drugs for that period of time was $64,315.86. We went to the card reimbursement plan.

We had the same amount of members basically filing for the same amount of drugs, give or take a few. That cost the following year in 1985 rose to $101,328.53. When we saw what was happening, we had a 1 year contract with that drug plan, PAID prescriptions, so we had to let the year run out before we could change back and the following year, we went back to prepaid drugs and our cost immediately dropped back into the $60,000 range.

Of course, that was in 1985 and the cost of the drugs even at that level have increased—as everybody else knows, including the of people who are here—somewhere between 15 to 20 percent in almost a year. So the only—that's the actual cost of the drugs. So the only way we can relate to that cost is strictly the administration fee that the drug store charges to handle that drug.

Now, some of my own personal experiences, I would get a drug filled, I'd go to pick the drug up and the pharmacy, thinking that I was going to pay cash, had one fee written down on the drug and when I handed him my prescription drug card, he said, oh, you've got a card. He immediately pulled the drug back, crossed the

number out, and raised it $3, $4, $5 for each one of the three drugs that I was picking up.

Mrs. BENTLEY. So what you're saying then is that the higher cost was not because of increased utilization by members. You're saying that this was added in as administrative costs?

Mr. GUTHRIE. Yes, by the pharmacists and again, we're not talking about an isolated pharmacy here. We're talking about pharmacies spread out all over the United States. So it's a good cross-sectional view.

Mrs. BENTLEY. Thank you.

Mr. Miller, do you have anything to say on that or Miss Nersesian?

Mr. MILLER. I'm sorry. I'm not quite clear. The instance you gave as an example at the end, what type of card did you have?

Mrs. BENTLEY. PAID.

Mr. MILLER. When the pharmacist increased your charge?

Mr. GUTHRIE. We had a little credit card by PAID Prescription Drugs in New Jersey, just like a credit card. You go into the drug store and you hand them your card and they take care of it and you don't pay anything out of your pocket and by the way, our drug plan that we have in our union is probably one of the best I've ever seen.

Ours is 100 percent paid. You have no copay or no deductible and we are trying to maintain that and we're having real difficulty in these inflated costs and also, we're trying to take care of our elderly and our retirees because what we do with our retirees, once they retire, they're not in the health and welfare plan per se because it's funded by a percent and a half of the gross labor income by the employer.

So when the retiree retires, he no longer is covered by that but we allow him to stay in the plan for $22.50 a month and we can't cover that retiree for that. We've been carrying him because as far as our retirees that are in the plan, for what they pay into the plan, they take out three times what they pay in but we're still trying to carry them as long as we can.

Your question?

Mr. MILLER. My question is and I guess it's also in part a response to your question, is that in an instance where a pharmacy has a prescription drug card system and they're processing your claim, for example, what they may sell to you at cash may be less than what they will bill PAID Prescriptions because PAID sets a limit that we will pay, the average wholesale price of this quantity of the drug plus a dispensing fee of a set amount, say $3.

What happens though is when the pharmacy bills that amount, PAID Prescriptions will say, well we have not updated our pricing for several months. So the price you were charging for this prescription drug is not what the price is that we have in our computer. So we're going to cut that and if you have dispensed more tablets than you have allowed, we're going to cut that, too.

So bear in mind what was submitted to the third party administrator is not what is paid to the pharmacy. The third party administrator's job is to cut that down to where it is appropriate although pharmacy would not agree that those discounts that they slash off are appropriate.

Mr. BANTA. Mr. Miller's correct, and I can't speak for PAID but at Blue Cross Blue Shield, we reimburse the pharmacists their actual acquisition cost not to exceed AWP plus the dispensing fee less the copay. When a claim comes in that exceeds that amount established by our computer, then we reduce that to the pharmacist. We update our prices more frequently than every 3 months. We update it weekly. So we are current with our prices.

Mrs. BENTLEY. You're very current on your prices?

Mr. BANTA. Right. I think that's one of the things I think a pharmacist would agree is a good feature about Blue Cross Blue Shield.

Mrs. BENTLEY. Mr. Guthrie, did you have any indication that during this time when they could just take a card and present it that there was an increase in the number of prescription drug purchases?

Mr. GUTHRIE. No. Our records indicate that the amount of claims were basically the same they were the previous year and even if you allowed for the inflation, this far exceeded the inflation. Also, what our basic plan provides for as far as the administrator is concerned—now the administrator who pays the people direct, they get a flat fee. So they don't benefit if a drug costs $10, $20 or $3. They bill us. We're self-insured. They bill us and we pay the actual claims plus their administration fee.

Now, they allow the druggist and this is one thing that really gets me—there's been some talk here about what they're allowed to inflate their cost, whatever, but I think there should be some control over how far they can go. For instance, they are allowed to charge the wholesale cost of the drug plus a 50 percent markup plus $1.65 administration fee for each drug filed. Now, on a monthly basis, we get a printout from the administrator in California and it gives us a complete list of every single member who filed a claim, how much it was, how much the wholesale cost of that drug is and how much they paid.

In a number of occasions, they do not reimburse the member the entire 100 percent cost because the drug store has inflated that cost more than 50 percent plus $1.65 and in regards to generic drugs, we're having a worse problem because we were encouraging generic drug usage but what is happening in generic drugs is they were getting reimbursed less for using generic drugs than they are for using the regular drugs and when we got a hold of the drug outfit in California and asked them why that was, it was because the pharmacy is inflating the generic drugs by more than they're inflating the regular drugs.

Mr. BANTA. It sounds like an interesting prescription drug plan. I would suggest if the gentleman wants, I'd be happy to talk to him about switching to Blue Cross Blue Shield.

I also might point out that these third party card plans were developed in the late 1960s, early 1970s, starting with the Motors up in Michigan and then the Title XVIII Amendments for Medicaid and so forth. Originally, the idea was and there's two ways to look at this in terms of utilization. We believe the third party prescription drug cards give greater access to patients to prescription drug coverage and that will naturally increase utilization.

I think about a year ago down in North Carolina, their Medicaid program was on a major medical basis, that is, a subscriber was re-

imbursed and then submitted claims and then the patient was reimbursed directly. They switched to a card program. The State government budgeted for the same amount of utilization. They were into the program, I think 6 months, and had to switch back. The utilization just shot up tremendously in that particular State.

So there's two ways to look at it. There's an access issue because some people just don't want to fool with the paperwork. They may pay the $3 and not send it in but if you have a card and you get a prescription and we even suspect and this is one of the reasons why we have copays, is to try to invest the patient in that process so that they won't get prescriptions filled that they won't actually need, if they're feeling better or whatever.

So there's different ways to look at that particular issue.

Mrs. BENTLEY. Of course, that's one of the concerns that a lot of people have had about a national health care plan. If it's too easy, sometimes things can be abused, too.

Go ahead, Mr. Miller.

Mr. MILLER. If I may, Mr. Banta is willing to sell his Blue Cross product to this gentleman, and I can tell you as a pharmacist, I will have 1,000 pharmacies lined up to take advantage of any program that pays AWP plus 50 percent plus $1.65 because nobody in the State of Maryland pays that much.

Mrs. BENTLEY. There you are. What are you rates, Mr. Miller?

Mr. MILLER. We are AWP plus $3.70 tops.

Mrs. BENTLEY. There you are. Are you going to make a deal?

Mr. GUTHRIE. That's the maximum they can charge.

Mr. MILLER. That's a maximum.

Mrs. BENTLEY. You're going to save some money.

Mr. GUTHRIE. That's the maximum they can charge for that claim, okay? I'm not saying all of them claimed 50 percent plus $1.65. All I'm saying is that's what the administrator will allow at that point.

Mr. MILLER. Then your administrator was not doing his job. Short and simple.

Mrs. BENTLEY. There you go. We've got two offers for you to save money.

Mr. GUTHRIE. I haven't found one yet that can cut our costs. I'll entertain bids from both of you.

Mrs. BENTLEY. Congressman Blaz?

Mr. BLAZ. I need to ask at this point, whether the cost of the drug from the manufacturer is the same to everybody.

Ms. NERSESIAN. Well, I think you heard testimony to the effect that under the Nonprofit Institutions Act we can make our drugs available to nonprofit hospitals at a reduced amount.

Mr. BLAZ. I'm talking about to—

Ms. NERSESIAN. To pharmacy?

Mr. BLAZ. Yes.

Ms. NERSESIAN. Well, we go through a wholesaler. Most of the industry goes through wholesalers, so it could possibly vary.

Mr. BLAZ. Per drug?

Ms. NERSESIAN. I can't really get into how each company markets but I'm speculating that since they do go through individual wholesalers, there's a possibility it could vary. I should provide that to you, though, for the record and confirm that for you.

Dr. PALUMBO. May I respond?

Mr. BLAZ. Yes, of course.

Dr. PALUMBO. There are some differences and it's usually based on volume. Wholesalers will offer certain discounts to community pharmacies off the AWP and that's generally based on the amount of volume of business that that pharmacy would do with that particular wholesaler. It doesn't vary a great deal but there is a little bit of variation in that.

I also would like to point out that some of the institutions that enjoy preferential pricing from the manufacturers are sort of taking a free ride on this Nonprofit Institutions Act. There's certainly nothing illegal about it but the act as originally designed was to take care of charitable institutions, yet these other entities do come under the umbrella of that act and so are legally entitled to negotiate for these lower prices.

Mr. BLAZ. May I ask a question of all four?

Mrs. BENTLEY. Sure.

Mr. BLAZ. If I were sitting in the back there and I came all the way from say, 60 miles away because the final solution to the spiraling costs is going to be at Essex Community College and good ole Helen Bentley's going to give it to us this afternoon. Y'all come down here.

Now, you all are here, and we heard all this, and I tell you, I'm an enlightened person this morning. I know more about pharmaceuticals and drugs and drug stores than I ever did, but to the person who came down here saying, I'm going to have to go back and tell the folks at the home what it's like down there, let me ask you this. Obviously being in the Congress, I can see how that it may have to be a Congressional action to resolve this issue because it's not just Maryland's problem. It's really a national problem. That much I can see.

If I were to ask each one of you this question, what do you suggest we do. Give me just one little idea. I need to also go back and tell someone what I can come out with. Think about it for a second and just say, if you were in my shoes and bear in mind now that I'm in the national legislation. So I have some concerns over the whole because what happens here is give or take, happens to other jurisdictions. We're all getting to the point that the elderly problem is a real serious problem. What would be one suggestion, lawyer, doctor, professor, Senor Palumbo?

Dr. PALUMBO. I'm going to have to get two cards just to put all those titles on. You know, I guess maybe we could get philosophical for a moment, if you wouldn't mind. We're one of the few civilized, industrialized nations that does not really have a national health policy of some sort. We are a Nation that has been built on the notion of capitalism.

We've done very well with that notion and I certainly am not trying to suggest that we back off from that but I think that perhaps it's time in the evolution of our country to start considering some sort of national health protection for our citizens, especially since our citizens are becoming much older.

In that vein, I think also that we need to start to consider what we're doing with the taxpayers' money when it comes to prescription drug prices. We've talked about multi-tier pricing and the

prices that are enjoyed by the Department of Defense and the Veterans Administration. These are entities that are paid for out of my tax dollars and your tax dollars and then I have to pay again because the drug companies cannot afford to offer lower prices to me in the community.

Perhaps we need to rethink what some of our Federal agencies are doing to the rest of the population by being able to take advantage of lower prices for just some of the population. So those are my thoughts on the issue.

Mr. BLAZ. A very good answer.

Anybody else care to comment?

Mr. BANTA. I agree I think, somewhat with Dr. Palumbo. I would say that we need to address the critical problem that the elderly are having specifically but that needs to be done and thought through in terms of the relationship with business which have been the traditional payers for employee health premiums.

Now, employers because of the same crunch that we're all looking at are cost-shifting that out to their employees but there's the insurance industry that's a player, there's business that's a player, it looks like government's going to be a player. We need to tread gently as we do this but I don't think there's any question that the problem with the elderly has to be addressed with these kinds of drugs.

Mrs. BENTLEY. Ms. Nersesian?

Ms. NERSESIAN. I would suggest that 6,000 Americans turn 65 every day and that in essence, the pharmaceutical industry has over $8 billion invested in research. Half of that is devoted to the chronic and degenerative diseases that afflict the elderly. I don't think that we want to tamper with an industry that is doing as well as it is with coming up with miraculous and life-saving drugs. We've got 16 drugs currently in development for Alzheimer's disease and I don't think any of us operate in a vacuum.

I know that my grandmother, who lives across the street from me, was in the hospital in December and most of January. Filling out her forms, I came to find that she generated a bill of $40,000. Nevertheless, she knows what I do and everyday, she reminds me of the fact that she is spending $125 a month for drugs.

I say Nanny, that keeps you out of the hospital at $20,000 a month and you know, I don't want us to take this industry for granted. So, I would take a close look at the FDA and the lag time. I would look at the Trade Representative and what they're trying to do to protect intellectual property and remind us that you're doing so and if we do come to find that our market period is extended, I'm hopeful that maybe some of your concerns will be allayed.

Mr. BLAZ. You're probably aware that the other day we introduced a bill in the House on Alzheimer's and related diseases, seeking $560 million to see if we could concentrate on that.

Mrs. BENTLEY. It's research.

Ms. NERSESIAN. It generates $80 billion in costs in the United States—Alzheimer's.

Mr. BLAZ. How much?

Ms. NERSESIAN. It's $80 billion annually—$80 billion.

Mrs. BENTLEY. Alzheimer's is costing the U.S. $80 billion annually?

Mr. BLAZ. You know, Helen, we've got to move here. When she gave the statistic about how many are turning 65 a day.

Mrs. BENTLEY. I know.

Mr. BLAZ. We've got to get going here.

Mr. BLAZ. How about you, Mr. Miller? Any pearls of wisdom?

Mr. MILLER. I think if I had the pearls of wisdom, I wouldn't be sitting here. I don't think there are any easy solutions. The pharmaceutical industry has produced miracles in this country of the products that have come to market. There is absolutely no denying that, but at the same time, there are problems within the industry and within the distribution system of pharmacy itself.

One, as Dr. Palumbo mentioned, I think one of the solutions could be the elimination of the nonprofit exemption under the Robinson-Patman Act which enables a nonprofit institution—and there is abuse of nonprofit status—to bid for and purchase drugs from the manufacturer and essentially coerce the manufacturers into providing them with deep discounts. That increases the payment that everybody else has to pay.

I think we as pharmacists would support the elimination of the distribution of free drugs, i.e., sampling, the practice of giving samples to physicians that end up in a corner cupboard—eventually somebody has to pay for those as well, that's built into the drug cost—with the end goal of hopefully evening out for everybody what everybody pays for the drugs so that no one gets special benefits.

As far as the elderly is concerned, again, there is no easy solution to that. That is a problem that we must address and whether it leads to national health insurance or a revision of the Medicare Catastrophic Coverage Act, I think those need to be looked at as well. In the meantime as a pharmacist, the advice I can give to any elderly patient is to make sure you establish a relationship with a pharmacist in your community. Work with him to question the drug products that you are on. It may not be necessary for you to be on everything that your physician has prescribed.

Sometimes you may have two physicians and they may not know that they are prescribing the same drug twice or related drugs. An educated consumer is probably going to be one of the best ways to help combat some of the rising prices.

Mrs. BENTLEY. I have a couple of questions here from the audience that I want to ask and then we will have one final wrap-up one.

How can a senior with no drug plan afford prescription drugs when one drug plan recently increased its prices 75 percent on April the 1st?

Mr. Banta?

Mr. BANTA. A good question. If I understand, the person has no drug coverage?

Mrs. BENTLEY. He has none.

Mr. BANTA. They're out-of-pocket expenses. That's a problem that needs to be answered in our society. We're in the business of providing insurance coverage. We're alarmed at what's happening

in the industry, as I've testified. That's a societal problem. I don't have a specific answer for that.

Mrs. BENTLEY. Dr. Palumbo?

Dr. PALUMBO. I certainly am not going to ask what the gentleman's income level is, but the State of Maryland does have a Pharmacy Assistance Plan for residents of the State who would not qualify for Medicaid but fall below some income limits. So that certainly is one avenue to investigate.

Mrs. BENTLEY. Any other suggestions on it?

All right. This deals with a specific medication, Feldene, F-E-L-D-E-N-E, which is priced at $145 for 100. The question is, why was the time limit extended before generics could be produced on that and do manufacturers recoup their expenses in the first 6 months?

Ms. NERSESIAN. Unfortunately, I can't get into pricing decisions of individual companies. I can try to provide you with that information. In terms of an extension, if it was extended, it was under the Patent Term Restoration Act of 1984 that was enacted when generics were able to come onto the market the day the patent expires. Congress went ahead and enacted legislation that would allow for the extension of a patent not beyond 2 years but only when the preclinical time exceeded a certain term.

So as far as commenting on the specific drug, I'm afraid I can't do it.

Mrs. BENTLEY. So the preclinical time may be involved in that?

Ms. NERSESIAN. Clinical and preclinical and the new drug approval times.

Mrs. BENTLEY. You've said that $8 billion a year goes into research, 34 percent of the—

Ms. NERSESIAN. That's according to Chairman Waxman's subcommittee.

Mrs. BENTLEY. Do we have any idea how long it takes a company to recoup its investment in a drug?

Ms. NERSESIAN. Most companies don't recoup. There are blockbuster drugs where companies do go ahead and fund the rest of their research from a particular drug. I think that you can find this in many instances and I think that up until the 1980s, you often came across drugs that were approved by the FDA that did not recoup their investment.

So it usually is specific drugs that a company has within its armamentarium that actually do recoup the investments. I know that there are certain bio-tech companies that will have one drug—they are placing a much higher percentage of their revenues, plowing that back into R&D, sometimes as high as 40 to 60 percent. I can't comment though on the specifics of that because I don't know them.

Mrs. BENTLEY. All right. What are the drug manufacturers and/or distributors doing about generic drugs that do not accomplish the same thing as the name brand drug?

Dr. Palumbo?

Dr. PALUMBO. Well, first of all, if they don't meet the Federal regulations, FDA will take them off the market or tell the company to take them off the market. So that's the first thing that would happen. The second thing is that the regulations do provide—and I believe Ms. Nersesian mentioned this earlier—for some variability

among generic products. I think the important factor here is to maintain the patient on the same product. If they start them on the brand name, to maintain them—with regard to those products where it might be important, or if they start them on the generic, to continue them on the generic.

I don't think the manufacturers themselves can really do much more than to buy into that particular philosophy. As a matter of fact, there are some occasions when the generic product is more bioavailable than the original brand name product. Digoxin was one example of that. Yet, the brand name product is the one that the FDA would use as the standard for comparison.

So sometimes the generic product might even be able to deliver more into the patient's bloodstream but that's not always good. What we're really interested in is stability over time. So, to maintain them on one product is usually a good idea or if you're going to switch them, to realize that there are going to be differences and watch them closely.

Mrs. BENTLEY. All right.

Ms. Nersesian, it has always been very fashionable to label the industry as the villain when people find out that they're paying more for specific drugs here than they are, let's say, in France or Norway, and that is to be expected. The specific one I am referring to is pentamidine. There have been reports that the pharmaceutical products are being sold in Europe for one-third less than here in the U.S.

I mean, people then think that all the R&D costs are being recouped here because everybody's paying the price here. What is happening?

Ms. NERSESIAN. I can understand where your constituents would be puzzled with that report. First, we need to look abroad and see what kinds of delivery systems we're looking at. For example, many countries have government-owned pharmacies or they restrict pharmacies to a number of inhabitants. So the delivery systems are often very different. In some countries, only doctors can dispense the drug.

I think that you need to look at currency fluctuations. One of our companies did a study of eight drugs and found that there was a 300 percent markup only due to the currency fluctuations.

So this may not be the answer that someone would like to hear but there are a lot of variables that have to be taken into consideration. You know that in the United States, we're a fairly litigious population. There are a lot of product liability costs that you don't see abroad and again you don't have the same kind of delivery systems. So I think that would be the response.

Mrs. BENTLEY. Do you think that when the European Community gets going in 1992 there will be an adverse or a plus reaction upon drug development and drug sales in this country?

Ms. NERSESIAN. Well, we're actively watching that situation as is our Trade Representative who's doing a very good job. We're watching the 12 countries to see what quotient they use, whether they're going to use the delivery system that West Germany has, whether they're going to use the English model. We're definitely involved. We've opened up an office in Brussels to watch the situation.

Mrs. BENTLEY. One final question. What impact is large-scale overseas pharmaceutical counterfeit and patent violations having on our domestic firms and is this cost being passed on to the U.S. consumer?

Ms. NERSESIAN. As were mentioned before, in particular there are four countries that are blatant violators and I think that the U.S.T.R. has gotten actively involved in trying to come up with some sanctions.

Mrs. BENTLEY. What are the four again?

Ms. NERSESIAN. They're Brazil and Argentina, India and Thailand are the four that—

Mrs. BENTLEY. And Thailand?

Ms. NERSESIAN. Yes. Are most closely being watched.

Mr. BLAZ. What's the second country?

Ms. NERSESIAN. It's India.

Mrs. BENTLEY. India?

Ms. NERSESIAN. Brazil, India, Argentina and Thailand.

Mr. BLAZ. Argentina.

Mrs. BENTLEY. What about Japan in this picture?

Ms. NERSESIAN. Japan is interesting in that I think we're faring fairly well in that market. We've got about 15 percent, which for most of industry, is faring fairly well. Per capita, they use prescription drugs quite a bit.

Mrs. BENTLEY. Quite a bit.

Ms. NERSESIAN. Quite a bit, yes.

Do you have any other questions, Ben?

Mr. BLAZ. None.

Mrs. BENTLEY. I want to thank the panelists for your participation this morning. I've learned a lot. As Congressman Blaz said a few minutes ago, he's learned a lot and I want to thank you for the time that you've given to us and been very patient with the questioning and Mrs. McLaughlin, also for your participation with it.

Thank you, Ben, once again for your joining with us today.

[Whereupon, at 12:52 p.m., the hearing was adjourned.]

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